EXHIBIT H

Page 1

UNITED STATES DISTRICT COURT SOUTHERN DISTRICT OF WEST VIRGINIA CHARLESTON DIVISION

IN RE: ETHICON, INC., \$ MASTER FILE
PELVIC REPAIR SYSTEM PRODUCTS \$ NO. 2:12-MD-02327
LIABILITY LITIGATION \$

MDL NO. 2327
THIS DOCUMENT RELATES TO: \$
DIANNE M. BELLEW, \$ JOSEPH R. GOODWIN \$
US DISTRICT JUDGE
Case No. 2:13-cv-22473

November 10, 2014

- - -

Videotaped deposition of PROF. DR. MED. UWE KLINGE, held at Quellenhof Hotel, Monheimsallee 52, 52062, Aachen, Germany, commencing at 9:04 a.m., on the above date, before Tami Cline, Registered Merit Reporter, Certified Realtime Reporter.

GOLKOW TECHNOLOGIES, INC. 877.370.3377 ph | 917.591.5672 fax deps@golkow.com

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1	APPEARANCES:	1	EXHIBITS		
2	ANDERSON LAW OFFICES, LLC		(CONTINUED)		
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3	1360 West 9th Street Suite 215	4	Klinge Trial Article entitled "Long-term 165		
4	Cleveland, Ohio 44113	5	Deposition 5 outcome and quality of life after open incisional hernia		
	216-592-8384		repair - light versus		
5	Ben@andersonlawoffices.net	6	heavyweight meshes"		
6	Representing the Plaintiffs	7	Klinge Trial Article entitled "Bias-Variation 169 Deposition 6 Dilemma Challenges Clinical		
	THOMAS COMBS & SPANN, PLLC	8	Trials: Inherent Limitations of		
7	BY: DAVID B. THOMAS, ESQUIRE	9	Randomized Controlled Trials and Meta-Analyses Comparing Hernia		
8	300 Summers Street Suite 1380		Therapies"		
6	Charleston, West Virginia 25301	10	Klinge Trial Article entitled "Prospective, 173		
9	Dthomas@tcspllc.com	11	Deposition 7 Long-Term Comparison of Quality		
10	BUTLER SNOW, LLP	12	of Life in Laparoscopic Versus Open Ventral Hernia Repair"		
11	BY: CHAD R. HUTCHINSON, ESQUIRE 1020 Highland Colony	13	Plaintiff's P0036 PowerPoint presentation 41		
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12	Ridgeland, Mississippi 39157		Plaintiff's PLT0067 Article entitled 26		
13	601-948-5711 Chad.hutchinson@butlersnow.com	15	"Complications from vaginally placed mesh in		
14	Representing Johnson & Johnson and Ethicon	16	pelvic reconstructive surgery"		
15	ALSO PRESENT:	17	Plaintiff's PLT0260 Article entitled "Impact of 49 Polymer Pore Size on the		
16	Gregory Fields, Videographer Julie Filarski, Anderson Law Offices, LLC	18	Interface Scar Formation in a Rat Model"		
17	Michael Kauffmann, Precision Trial Solutions	19 20	Plaintiff's PLT0271 Article entitled "The lightweight and large porous concept for hernia repair"		
18		20	Plaintiff's PLT0697 Article entitled "Elongation 60 of textile pelvic floor		
19 20		22	implants under load is		
21 22			related to complete loss of effective porosity, thereby		
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3	EXHIBIT NO. PAGE	3	My name is Gregory Fields. I'm the videographer
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4	EXHIBIT NO. PAGE Plaintiff's PowerPoint slide entitled 74 Demonstrative "Pores Collapse Under Page 17 Tension," referencing P2995,	3 4 5	My name is Gregory Fields. I'm the videographer for Golkow Technologies. Today's date is 11/10/2014, and the time is 9:04 a.m. This video
4	EXHIBIT NO. PAGE Plaintiff's PowerPoint slide entitled 74 Demonstrative "Pores Collapse Under P3361 Tension," referencing P2995, ETH.MESH.05237872, PLT 0697,	3 4 5 6	My name is Gregory Fields. I'm the videographer for Golkow Technologies. Today's date is 11/10/2014, and the time is 9:04 a.m. This video deposition is being held in Aachen, Germany, in
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4 5 6	EXHIBIT NO. PAGE Plaintiff's PowerPoint slide entitled 74 Demonstrative "Pores Collapse Under P3361 Tension," referencing P2995, ETH.MESH.05237872, PLT 0697, P1452 - ETH.MESH.000007 Plaintiff's PowerPoint slide entitled 79 Demonstrative P3362 "Prolift Unsafe/Defective	3 4 5 6 7 8	My name is Gregory Fields. I'm the videographer for Golkow Technologies. Today's date is 11/10/2014, and the time is 9:04 a.m. This video deposition is being held in Aachen, Germany, in the matter of In Re: Pelvic mesh, for the Superior Court of New Jersey, Atlantic County.
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3 (Pages 6 to 9)

	Page 10		Page 12
1	MR. ANDERSON: It's MDL.	1	and some years later on I got specified as an
2	THE VIDEOGRAPHER: Okay. Okay.	2	abdominal surgeon.
3	THE COURT REPORTER: Would you raise your	3	Q. Tell the jury a little bit about your
4	right hand, please.	4	practice of abdominal surgery.
5	Do you swear or affirm the testimony you give	5	A. While working at this surgical department, I
6	in this cause will be the truth, the whole truth	6	performed some thousands of operations, mainly done
7	and nothing but the truth?	7	for diseases of the abdominal cavity of the intestine
8	THE WITNESS: I swear.	8	of the abdominal wall, but it covers almost all parts
9	THE COURT REPORTER: You can put your hand	9	of the body.
10	down.	10	Q. Have you used synthetic surgical mesh in your
11	PROF. DR. MED. UWE KLINGE, called as a	11	surgical practice?
12	witness by the Plaintiff, having been first duly	12	A. Yes, I did.
13	sworn, testified as follows:	13	Q. Did you use hernia meshes in your surgical
14	DIRECT EXAMINATION	14	practice that were manufactured by Ethicon?
15	BY MR. ANDERSON:	15	A. Yes, I did.
16	Q. Good morning, Dr. Klinge.	16	Q. Doctor, what caused you to study the
17	A. Good morning.	17	biomaterial science of surgical meshes?
18	Q. Dr. Klinge, please tell the jury what your	18	A. When we started to use surgical meshes in the
19	profession is.	19	beginning of the '90s, we got aware that we have to
20	A. I'm an abdominal surgeon and a biomaterial	20	face several complications that are related with
21	researcher.	21	these mesh materials, mainly at the occasion of some
22	Q. Where do you work, Dr. Klinge?	22	revision operations where we saw what happens to
23	A. I'm working at the University of Aachen.	23	these meshes after getting incorporated; and we
24	Q. And is that Aachen, Germany?	24	wanted to learn more about these meshes to avoid
	Page 11		Page 13
1	A. It's Aachen, Germany.	1	these complications.
2	0 4 1 4 4 1 4 1 9		_
_	Q. And is that where we are today?	2	Q. And when did you first begin that work?
3	A. Exactly.	2 3	A. We started to think about it in the beginning
	A. Exactly.Q. Please tell the jury a little bit about		
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3 4	A. Exactly.Q. Please tell the jury a little bit aboutAachen University Hospital.A. It's a large teaching and research hospital,	3 4	A. We started to think about it in the beginning of the '90s, and the research project really started in 1994. Q. And as part of your work in looking at the
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	Page 14		Page 16
1	A. Yes.	1	structure as for Prolene Soft.
2	Q. Okay. Dr. Klinge, all of your opinions today	2	Q. So Prolene, Prolene Soft and Gynemesh PS, is
3	will need to be to a reasonable degree of medical and	3	it your testimony they are all brand names for
4	scientific certainty. Do you understand that?	4	polypropylene mesh made by Ethicon?
5	A. Yes.	5	A. Yes.
6	Q. Have you published articles in the	6	Q. Okay. What is the mesh material that's in
7	peer-reviewed medical literature that relate to the	7	the Prolift device?
8	safety of surgical meshes either for the abdomen or	8	A. It is polypropylene.
9	the pelvic floor?	9	Q. And what is the brand name from Ethicon for
10	A. Yes, I did.	10	this polypropylene in the Prolift device?
11	Q. How many times?	11	A. It's Gynemesh PS.
12	A. With the specific topic of surgical meshes,	12	Q. Okay. Have you reviewed and do you rely upon
13	it's more than 100.	13	Ethicon internal documents and depositions of Ethicon
14	Q. Have you written books and book chapters that	14	witnesses that you reviewed over the course of this
15	relate to the safety of surgical meshes for both the	15	case in arriving at your opinions that you are going
16	abdomen and the pelvic floor?	16	to offer here today?
17	•	17	A. Yes.
	A. Yes, I did.		
18	Q. And on how many times?	18	Q. With regard to the Prolift, are you familiar
19	A. About 50.	19	with the weight and surface area, the weave pattern
20	Q. Have you been asked to speak at conferences	20	and the pore size
21	around the world on the topic of surgical mesh	21	A. Yes.
22	complications and safer mesh design for the abdomen	22	Q of Prolift mesh?
23	and the pelvic floor?	23	A. I'm sorry.
24	A. Yes, I have been, and I'm still.	24	Q. All right.
	Page 15		Page 17
			5
1	O. Have you been asked by Ethicon to speak as an	1	A. Yes, I am.
1 2	Q. Have you been asked by Ethicon to speak as an invited lecturer at conferences sponsored by Ethicon?	1 2	A. Yes, I am.
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5 (Pages 14 to 17)

	Page 18		Page 20
1	PowerPoint slide titled "Foreign Body Reaction: More	1	anterior implant.
2	Foreign Body = More Inflammation," Bates stamped	2	Q. Doctor, did I ask you to bring with you to
3	P1005 ETH.MESH.02341454, marked for identification.)	3	your testimony today a Prolene suture?
4		4	A. Yes.
5	BY MR. ANDERSON:	5	MR. ANDERSON: And, Counsel, for purposes of
6	Q. Doctor, I'm showing you the first slide,	6	the record, it's a demonstrative exhibit, which
7	which is a demonstrative exhibit, which we have gone	7	we have premarked as Plaintiff's Exhibit P3363.
8	ahead and labeled as Plaintiff's Exhibit P3358. Is	8	
9	this slide entitled, "Foreign Body Reaction," a slide	9	(Plaintiff's Exhibit No. P3363, Prolene
10	that you helped prepare for the jury today?	10	suture, was marked for identification.)
11	A. Yes.	11	
12	Q. What does foreign body reaction refer to?	12	BY MR. ANDERSON:
13	A. Foreign body reaction mainly consists of an	13	Q. Doctor, is this the Prolene suture you
14	inflammatory reaction and a scar reaction. And if	14	brought here to the deposition today?
15	you assume you get a splinter or foreign body into	15	A. Yes. Exactly.
16	your tissues. The body tries to get rid of it, and	16	Q. Can you please first show the Prolene suture
17	if they if the body is not able to get rid of this	17	to the jury? If you would just lay it on that piece
18	foreign body, it's sent a lot of white blood cells to	18	of paper so the our kind videographer here can
19	this to build a wall to protect the surrounding	19	pick up on that.
20	tissue from this foreign body. And this	20	A. (Complying.)
21	inflammatory these inflammatory cells are then	21	Q. Thank you.
22	surrounded by dense scar tissue.	22	Now, Doctor, you have placed sutures like
23	Q. And when we see on this slide "more foreign	23	this in patients?
24	body equals more inflammation" you have put that	24	A. Yes. This is a typical suture we are using
	Page 19		Page 21
1	there. Why have you put that there for the jury?	1	in the OR, but usually we made some knots about it
2	A. Sorry?	2	and we removed the rest of the fibers. So, actually,
3	Q. "More foreign body equals more inflammation,"	3	we left 1 to 2 centimeters of this suture in the body
4	why have we put that there? Why is that significant	4	when we made a stitch with this material.
5	to your opinions, Doctor?	5	Q. So given that you trim this after you do the
6	A. Yeah. It was one of our or it was	6	stitch, show the jury, if you would, how much
7	confirmed by all of our studies that, of course, the	7	polypropylene stitch is left.
8	more foreign body you have, the more inflammation you	8	A. So, of course, it depends from thickness of
9	have. The more surface you have, the more	9	the tissue, but usually it's not more than this.
10	inflammation you have. So if you have two splinters,	10	Q. What is that?
11	you will have more inflammation than if it is only	11	A. What remains in the tissue after
12	one.	12	Q. About 2 inches?
13	Q. Doctor, I believe by this time in the trial	13	A. An inch is 2.5 centimeters, so it is it is
14	that the jury would have already seen a Prolift	14	less than one inch.
15	anterior mesh. I we have one there on the slide.	15	Q. Okay. By way of example, Doctor, did I ask
16	Did I ask you to calculate the amount of	16	you to measure you said there was 240 meters of
l	polypropylene fiber that is woven into a Prolift	17	polypropylene material in an anterior mesh?
17		18	A. Yes.
17 18	anterior mesh?	1 -0	
	anterior mesh? A. Yes, I did.	19	
18			(Plaintiff's Exhibit No. P3364, 240 meters of
18 19	A. Yes, I did.	19	(Plaintiff's Exhibit No. P3364, 240 meters of polypropylene, marked for identification.)
18 19 20	A. Yes, I did.Q. And please tell the jury how much	19 20	
18 19 20 21	A. Yes, I did.Q. And please tell the jury how much polypropylene suture material is in a Prolift	19 20 21	

Page 24 Page 22 Exhibit P3364. Did I ask you to measure out 240 1 1 A. Yes. 2 meters of polypropylene? 2 Q. Just briefly tell the jury in your own words 3 A. Yes. I --3 what mesh contraction or mesh shrinkage is. 4 Q. Could you, please -- and did you measure that 4 A. When we are talking about mesh shrinkage, we 5 5 usually are thinking of the contraction of the scar 6 A. Yeah. I did it myself, and I actually walked 6 tissue around the mesh. 7 7 20 times in my room or at my house --Q. And is scar tissue -- is there another -- is 8 8 fibrosis also another word for scar tissue? 9 9 A. -- to get this -- the length of this suture A. Yes. Fibrosis is -- the fibrosis around the 10 10 mesh is usually the scar tissue. 11 Q. If you would just lay that on the piece of 11 Q. So if this piece of paper is the mesh as it's 12 material next to it. 12 in the body, can you explain to the jury what we're 13 A. Yeah. 13 talking about in terms of mesh shrinkage or 14 Q. Now, Doctor, we're not as familiar in the 14 contraction if that's the implant and the black here 15 15 United States with the metric system. How many yards is -- the table is the tissue? 16 A. When the mesh is usually incorporated into 16 of material does 240 meters relate to? 17 17 the scar tissue, and we know that scar contracts. It A. It is equal to 260 yards. 18 Q. And you know in the US we play football, and 18 lose a lot of water, and, therefore, when the scar is 19 a football field is 100 yards long. So is this more 19 contracting, it is pushing together the implant like than two and a half football fields of material 20 this. It can be up to 90 percent that the mesh 20 21 21 that's woven into a Prolene anterior mesh? material is reduced by this contraction of the scar. 22 A. Exactly. Or if you don't play football, it 22 Q. Have you published in the peer-reviewed 23 is three times the height of the Statue of Liberty in 23 literature on the subject of mesh shrinkage and 24 New York. 24 contraction and the resulting clinical consequence to Page 23 Page 25 1 Q. Okay. All right. Thank you. 1 patients? 2 Doctor, do you have an opinion to a 2 A. Yes, I did. 3 3 reasonable degree of medical and scientific certainty Q. How many publications over what period of 4 as to whether there will be a different amount of 4 time relate to mesh shrinkage and mesh contraction 5 5 foreign body reaction and inflammation in a patient's that you have authored? 6 tissues to less than one inch of suture material of 6 MR. THOMAS: Objection, without more 7 polypropylene versus more than two and a half 7 specificity into what area of the body. 8 8 football fields of polypropylene material? Do you BY MR. ANDERSON: 9 have an opinion? 9 Q. Doctor, have you published in the 10 A. Yes. 10 peer-reviewed literature on the subject of mesh 11 Q. And what is that opinion? 11 shrinkage and contraction of polypropylene meshes, 12 A. If you place this huge amount of material in 12 like the Prolift mesh, resulting in clinical 13 a comparatively small area, you will have a 13 consequences to patients? 14 14 significantly higher intensity and amount of A. Yes. 15 inflammation and scar tissue as a reaction to this 15 MR. THOMAS: Same objection. 16 huge amount of material. 16 BY MR. ANDERSON: 17 17 Q. Okay. Doctor, we can put those to the side Q. How many times have you done that, Doctor? for the moment. 18 18 A. It's more than 50. 19 I would like to now -- sorry. I would now 19 Q. Doctor, in terms of inflammatory response and 20 like to talk to you about the relationship between 20 this foreign body reaction that we have been talking 21 this foreign body reaction to polypropylene mesh and 21 to, will that -- will there be any difference between 22 a concept known as mesh contraction or mesh 22 a surgical mesh implanted, for instance, in the 23 23 shrinkage. Are you familiar with those terms, mesh abdominal wall and these principles versus a surgical 24 shrinkage or mesh contraction? 24 mesh implanted in the pelvic floor?

	Page 26		Page 28
1	MR. THOMAS: Objection; foundation.	1	MR. THOMAS: Just note my objection to this
2	THE WITNESS: The wound contraction is not	2	before you show the jury what the picture is
3	restricted to the abdominal wall. It happens in	3	until we have an adequate foundation for the jury
4	the entire body. The foreign body responds. The	4	to see the picture.
5	scarring around a foreign body happens in every	5	BY MR. ANDERSON:
6	part of the body, and in this regard the response	6	Q. And you reviewed this article in coming to
7	of the tissue to the to a mesh, it's quite	7	your opinions in this case?
8	similar whether it is in the pelvic floor or	8	A. Yes.
9	whether it's in the abdominal cavity.	9	Q. And does this article involve the Prolift
10	BY MR. ANDERSON:	10	mesh?
11	Q. Doctor, I now want to explain to the jury	11	A. Yes.
12	what the consequences to the patient are of severe	12	Q. And if we're looking at this image contained
13	inflammation and contraction of polypropylene mesh	13	within the article, what are we looking at here,
14	like Prolift. Okay?	14	Doctor?
15	A. Yes.	15	A. It is showing the explanted mesh material
16		16	that is in taken off in several parts, and you see
17	(Plaintiff's Exhibit No. PLT0067, Article	17	that it is incorporated into a lot of scar tissue,
18	entitled "Complications from vaginally placed mesh in	18	that it is deformed, that it's not laying very flat
19	pelvic reconstructive surgery", was marked for	19	in this area.
20	identification.)	20	MR. THOMAS: Just show
21		21	THE WITNESS: It's hard to identify the
22	BY MR. ANDERSON:	22	textile structure in this compound of scar.
23	Q. I'm handing you what has been marked as	23	MR. THOMAS: I just want to show my
24	Plaintiff's Exhibit 0067. It is PLT0067.	24	continuing objection for lack of foundation.
	Page 27		Page 29
1		1	Page 29 MR. ANDERSON: Noted.
1 2	Page 27 MR. THOMAS: This has a sticky on it. Is that yours?	1 2	
	MR. THOMAS: This has a sticky on it. Is		MR. ANDERSON: Noted.
2	MR. THOMAS: This has a sticky on it. Is that yours?	2	MR. ANDERSON: Noted. BY MR. ANDERSON:
2	MR. THOMAS: This has a sticky on it. Is that yours? MR. ANDERSON: What I have done for you,	2 3	MR. ANDERSON: Noted. BY MR. ANDERSON: Q. As a hernia surgeon, did you remove
2 3 4	MR. THOMAS: This has a sticky on it. Is that yours? MR. ANDERSON: What I have done for you, Counsel, is on every one of these documents,	2 3 4	MR. ANDERSON: Noted. BY MR. ANDERSON: Q. As a hernia surgeon, did you remove contracted polypropylene meshes from patients?
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Page 30 Page 32 the -- any specific causation testimony of 1 compare to contracted mesh removed due to 2 Ms. Bellew is not contained in his report. Am I 2 complications like we've seen in these -- in these 3 3 recent photographs from the Blandon article as well incorrect? MR. ANDERSON: We're not going to talk about 4 4 as this from Ms. Bellew? 5 causation. 5 A. The mesh, when it's taken out of the box, 6 MR. THOMAS: Okay. Show my objection to any 6 usually is very soft, pliable, flexible, whereas a 7 7 plaintiff-specific testimony by Dr. Klinge. mesh that is integrated into this scar tissue usually 8 8 MR. ANDERSON: I'll show your objection. is rigid, stiff, not flexible, not stretchable any 9 9 longer; and, therefore, it is going to be in sharp 10 (Plaintiff's Exhibit No. P3356, Page 20 of 10 contrast to the properties of the surrounding tissue. 11 1386 from Howard Jordi's expert report containing 11 Q. Doctor, did you prepare a slide for the jury photographs, was marked for identification.) 12 regarding mesh inflammation and contraction and their 12 13 13 relation to consequences for the patient? 14 BY MR. ANDERSON: 14 A. Yes. 15 15 Q. I'm handing you what's been premarked as Plaintiff's Exhibit 3356. Is that one of the 16 16 (Plaintiff's Demonstrative Exhibit No. P3359, photographs that you saw from Dr. Jordi's report of 17 PowerPoint slide entitled "Patient Injury Due to Mesh 17 18 explanted mesh from Ms. Bellew? 18 Inflammation and Contraction", was marked for 19 A. Yes, it is. 19 identification.) 20 20 Q. Was this image significant to your opinions 21 21 in this case? BY MR. ANDERSON: 22 A. Yes. 22 Q. I'm showing you what we have marked as 23 Q. Can you please explain the significance of 23 Plaintiff's Exhibit P3359. Is that the slide? 24 that image in relation to what we just -- what the 24 A. Yes. Page 31 Page 33 jury just saw? 1 1 Q. Okay. 2 A. This image --2 MR. ANDERSON: If you could just bring in the 3 3 MR. THOMAS: Excuse me. Let me place my first bullet points. MR. THOMAS: Just show my objection to this 4 objection. I object to this because it is not a 4 5 5 disclosed opinion in the report that Ben here -demonstrative and testimony about this because 6 6 the patient has not been designated for the that's at issue in this deposition and also 7 because this witness is designated on general 7 quantitative risks of complications in the pelvic 8 8 causation issues and not on plaintiff-specific floor. 9 issues. 9 BY MR. ANDERSON: 10 BY MR. ANDERSON: 10 Q. Doctor, if we look here to these first two 11 Q. Does the appearance of Ms. Bellew's 11 bullet points, can you tell us why you created these 12 contracted mesh in -- does the appearance of the mesh 12 for the jury? 13 in -- from Dr. Jordi's report -- what do you see from 13 A. One of our important findings in these years 14 that -- from that image, sir? 14 of research together with Ethicon was that this mesh 15 A. On this photograph you see the folding of a 15 inflammation, this inflammatory region around the 16 mesh that is incorporated into very big amount of 16 foreign body, it's a permanent one. It is -- it 17 scar tissue, and it is a confirmation that this 17 doesn't stop after three weeks or four weeks, but it phenomenon is not limited to the abdominal wall, but 18 18 stays there as a chronic wound until the end of the 19 it happens in every part of the body. 19 life of the patient; and this chronic wound leads to 20 Q. Now, Doctor, you have seen the Prolift 20 a permanent tissue irritation. 21 anterior mesh as it comes out of the box? Have you 21 In some patients there's always some sort of 22 seen that? 22 scarring that is protecting the surrounding tissues 23 A. Yes. 23 from the foreign body, but in some patients this 2.4 O. How does the Prolift mesh out of the box 24 scarring is very, very severe; and it leads that

	Page 34		Page 36
1	almost all the entire area where the mesh was been	1	polypropylene meshes that have been explanted?
2	placed is blocked by this scarring.	2	A. We always found similar tissue response, and
3	MR. THOMAS: Just show my objection to any	3	we didn't find any significant difference in the
4	testimony to Bullets 2, 3 and 4 because it calls	4	tissue reaction.
5	for testimony about risks in the pelvic floor	5	Q. And with regard to the first two bullet
6	which is beyond this witness's expertise.	6	points on the slide that we were talking about a few
7	BY MR. ANDERSON:	7	minutes ago, mesh inflammation is permanent and in
8	Q. Doctor, over the course of your 20 years of	8	some patients mesh scarring is severe. Have you
9	research, how many explants from the abdominal wall	9	arrived at those opinions based upon your 20 years of
10	have you looked at and analyzed?	10	work, all of your peer-reviewed publications, the
11	A. We have meanwhile several thousand of	11	conferences you've spoken at around the world, the
12	explanted meshes here that we have had a look to and	12	conferences to urogynecologists and urologists at the
13	we try to analyze.	13	request of Ethicon, your review of thousands of
14	Q. As part of this body of work over the last 20	14	hernia mesh explants and your review of hundreds of
15	years, how many explanted meshes from the pelvic	15	pelvic floor explants and over 50 that you have
16	floor have you analyzed?	16	reviewed yourself?
17	A. It's up to 500.	17	MR. THOMAS: Objection.
18	Q. Okay. So with regard to these thousands of	18	THE WITNESS: Yes, exactly.
19	hernia mesh explants from humans that you have	19	MR. THOMAS: Object to the form of question.
20	analyzed and hundreds of pelvic floor explants that	20	THE WITNESS: It is.
21	you've analyzed over the course of these 20 years,	21	MR. ANDERSON: Whatever.
22	have you recognized similarities between the	22	BY MR. ANDERSON:
23	contraction of the explanted abdominal wall meshes	23	Q. Go ahead.
24	and the explanted pelvic floor meshes?	24	A. The permanence of the mesh inflammation, it's
	Page 35		Page 37
			rage 37
1	MR. THOMAS: Show my objection to this to the	1	a fact and that in some of these cases you have an
1 2	extent it's based upon his review of the	1 2	a fact and that in some of these cases you have an extended scarring. It is a fact. It is not related
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Page 38 Page 40 1 scar tissue, that, of course, you have a higher 1 Q. Are these documents significant to your 2 risk for chronic pain, because of a higher risk 2 opinions -- strike that. 3 3 for getting nerves that are entrapped into the Have you seen in the internal documents and 4 scar tissue; and in the area of the pelvic floor 4 depositions of Ethicon witnesses discussions 5 you have a higher risk of dyspareunia, erosions 5 regarding patient complications related to mesh 6 and organ dysfunction. And, therefore, the 6 contraction? 7 extent of inflammation and scarring is a very big 7 A. Yes. 8 concern for the patient's safety. And if you 8 Q. Are these documents significant to your 9 9 have a lot of inflammation, a lot of scar, this opinions in this case? 10 carries a lot of risks for the patients. 10 A. Yes. 11 BY MR. ANDERSON: 11 Q. Have you studied and published in the 12 12 peer-reviewed literature on the amount of shrinkage Q. Is there any way for a surgeon who is 13 13 or contraction that will occur in the human body to implanting a Prolift mesh or a hernia mesh to know 14 the extent of scarring and contraction that will 14 polypropylene surgical meshes? 15 15 occur over the patient's life in and around the mesh A. Yes. 16 16 Q. What have your studies shown regarding the or a way to control it? 17 17 amount of shrinkage that occurs with polypropylene A. Not in regard to the specific response of a 18 patient, but for the general statement that the more 18 meshes in the human body? 19 material, the more inflammation, then, of course, you 19 A. Roughly you have to estimate a shrinkage, a 20 contraction of about 30 to 50 percent, but it depends 20 can estimate it. 21 21 Q. Based upon your years of consulting with on the design of the mesh. So it can be much more; 22 Ethicon and all of your work over the last 20 years, 22 it can be a little bit less. 23 and your work with Ethicon, do you have personal 23 Q. How does the amount of foreign body material 24 knowledge as to whether Ethicon was aware of these 24 in the mesh relate to the amount of mesh shrinkage or Page 39 Page 41 1 issues with contraction and inflammation of their 1 contraction that will occur in the tissue? 2 polypropylene meshes that you have discussed? 2 A. The more material, the more inflammation, the 3 MR. THOMAS: Objection to what Ethicon knew. 3 more scar, the more contraction, the more shrinkage. 4 BY MR. ANDERSON: 4 Q. Dr. Klinge, in the internal documents that 5 5 Q. Again, based upon your personal knowledge as you have reviewed from Ethicon, have you seen 6 a consultant with Ethicon, did you have discussions 6 anywhere where they mention or address these concerns 7 with them about the contraction of their 7 over the amount of material with their Prolift mesh? 8 8 polypropylene meshes? A. Yes, I did. 9 A. Yes, I definitely know that we have discussed 9 10 10 (Plaintiff's Exhibit No. P0036, PowerPoint this during our working group meetings with people presentation entitled "Stand & Deliver - Pelvic Floor 11 from Ethicon, exactly this problem of shrinkage, and 11 12 12 we have been trying to figure out what are the main Repair", was marked for identification.) 13 reasons. So, yeah, it was a finding from Ethicon as 13 14 well as from us --14 BY MR. ANDERSON: 15 15 Q. And did you --Q. I'm showing you what has been marked as 16 A. -- working hand in hand. 16 Plaintiff's Exhibit P0036. 17 Q. I'm so sorry. 17 Is this document something that you have 18 18 And in this working hand in hand with Ethicon reviewed during your work in this litigation? 19 in coming to these questions regarding mesh shrinkage 19 A. Yes, I did. 20 and its relationship to patient complications, did 20 Q. Is it significant to your opinions in this 21 you publish, while you were a consultant with 21 case? 22 Ethicon, in the peer-reviewed literature on these 22 A. Yes. 23 issues? 23 MR. THOMAS: What is the date of this 24 24 A. Yes. document?

	Page 42		Page 44
1	MR. ANDERSON: It's in your production, and	1	Initiation, August 25, 2008, was marked for
2	so any Ethicon production, according to the	2	identification.)
3	metadata, I believe it's 2008, but we can	3	
4	certainly check that on a break.	4	BY MR. ANDERSON:
5	MR. THOMAS: Thank you. Just note my	5	Q. Okay. I'm showing you what has been marked
6	objection to the use of any company documents	6	as Plaintiff's Exhibit 1156.
7	after the date of Mrs. Bellew's surgery.	7	Are you familiar with this document,
8	MR. ANDERSON: Oh, this is certainly before	8	Dr. Klinge?
9	Ms. Bellew's surgery.	9	A. Yes, I am.
10	MR. THOMAS: I just wanted to make sure.	10	Q. Is this something that you reviewed during
11	Thank you, Ben.	11	your work in this litigation?
12	BY MR. ANDERSON:	12	A. Yes, I did.
13	Q. Is this document significant to your opinions	13	Q. And is it significant to your opinions here
14	in this case?	14	today?
15	A. Yes.	15	A. Yes, it is.
16	Q. Just explain briefly what this document is,	16	Q. If we turn to page 12 of the document, is
17	Dr. Klinge.	17	this slide significant to your opinions?
18	A. It's a PowerPoint presentation from Ethicon.	18	A. Yes.
19	Q. Okay. If you go to page 7 of the document in	19	MR. ANDERSON: Can you blow up the right-hand
20	this Ethicon PowerPoint, you have seen this slide?	20	side of that?
21	A. Yes.	21	BY MR. ANDERSON:
22	Q. Okay. Is this important to your opinions?	22	Q. Doctor, is this part of the PowerPoint slide
23	A. Yes, it is important.	23	significant? And, if so, why?
24	Q. Can you explain why, please?	24	A. In this PowerPoint presentation from 2008
	Page 43		
	rage 13		Page 45
1		1	_
1 2	MR. ANDERSON: Blow up the yes.	1 2	from Ethicon, it is clearly stated that we need less
	MR. ANDERSON: Blow up the yes. THE WITNESS: The topic of this slide is		from Ethicon, it is clearly stated that we need less foreign body material. We need materials that
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2 3 4	MR. ANDERSON: Blow up the yes. THE WITNESS: The topic of this slide is "Improved Tissue Response," and so to get an	2 3 4	from Ethicon, it is clearly stated that we need less foreign body material. We need materials that correlate to the physiological characteristics. So it expresses that these people want to have less material to make it safer.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	MR. ANDERSON: Blow up the yes. THE WITNESS: The topic of this slide is "Improved Tissue Response," and so to get an improved tissue response, the people that make this presentation, they cited my work with Klosterhalfen MR. ANDERSON: If you could blow that up. THE WITNESS: where we wrote down the entire concept of the lightweight and large pore concept, and they figured out that for an improved tissue response, you need a large porous construction to reduce the tissue response. So they are in line completely with what we have found during these years, and they accepted it, obviously. BY MR. ANDERSON: Q. And is this in line how does this relate to your opinions regarding the amount of foreign body reaction and the amount of inflammation? A. It's exactly in accordance. So, yeah.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	from Ethicon, it is clearly stated that we need less foreign body material. We need materials that correlate to the physiological characteristics. So it expresses that these people want to have less material to make it safer. Q. Based upon your review of all of the materials in this litigation and all the depositions as well as your years of consulting with Ethicon, did you determine whether or not they ever manufactured a pelvic organ prolapse mesh with mesh that was actually designed for the pelvic floor? A. No, I didn't didn't find any any information to this. Q. The Gynemesh PS mesh and Prolift, was that designed by Ethicon as a hernia mesh or a pelvic floor mesh? A. To my knowledge, it was designed as a material-reduced hernia mesh. Q. Okay. Dr. Klinge, I want to shift gears here a little and talk to you about another mesh design characteristic, and that is the pores. What are mesh

	Page 46		Page 48
1	Q. Is the size of the pores or these open spaces	1	the critical pore size or open space must be for a
2	in the mesh material something that you have studied	2	surgical mesh implant for both hernia repair and
3	over the last 20 years, published on in the	3	pelvic floor repair in order to be safe in the
4	peer-reviewed literature, consulted with Ethicon	4	tissues?
5	about and presented at conferences around the world	5	A. Yes.
6	over the last 20 years?	6	Q. And what is that opinion?
7	A. We did it extensively.	7	A. The larger the pores, the safer it is to
8	Q. Is it also these open spaces or these pores a	8	the larger the pores, the lower the risk for this
9	design principle that you have used to work with	9	bridging; and for polypropylene, the critical figure
10	manufacturers to design safer meshes?	10	is about 1 millimeter.
11	A. Yes.	11	Q. And, again, we're on the metric system, but I
12	Q. Can you tell us what the significance of	12	know the jury is going to see documents that some of
13	these pores or open spaces are with regard to the	13	them are in millimeters and some are microns. What
14	tissue response for patients?	14	does 1 millimeter equal in terms of microns?
15	A. The size of a pore means a critical parameter	15	A. It equals 1,000 microns.
16	to predict what happens when the tissue is or when	16	Q. So 1 millimeter equals 1,000 microns?
17	the mesh is incorporated into the tissue. If you	17	A. Yes.
18	have very small pores, then the or the space in	18	Q. So would I'm not real good at math, so
19	between the fibers is completely filled by scar	19	would 3 millimeters equal 3,000 microns?
20	tissue; and that makes the mesh stiff and rigid,	20	A. Exactly.
21	whereas if you have very large pores, large distances	21	Q. Okay. I got that one right.
22	between the fibers, the body is able to fill the	22	I know that you said you have over 1,000
23	pores with fat tissue, and then the mesh remains	23	publications in the peer-reviewed literature on the
24	flexible, stretchable. So the small pores means a	24	safe design of surgical meshes. We obviously can't
	Page 47		Page 49
1	considerable risk for the patient, whereas the larger	1	go through all of those today, but I did want to show
2	considerable risk for the patient, whereas the larger the pore, the less of the risk.	2	go through all of those today, but I did want to show the jury just a couple of your peer-reviewed
2	considerable risk for the patient, whereas the larger the pore, the less of the risk. Q. Is another way to say the larger the pore,	2	go through all of those today, but I did want to show the jury just a couple of your peer-reviewed publications contained in your research on the
2 3 4	considerable risk for the patient, whereas the larger the pore, the less of the risk. Q. Is another way to say the larger the pore, the greater the distance between the fibers of the	2 3 4	go through all of those today, but I did want to show the jury just a couple of your peer-reviewed publications contained in your research on the relationship between inflammation and contraction and
2 3 4 5	considerable risk for the patient, whereas the larger the pore, the less of the risk. Q. Is another way to say the larger the pore, the greater the distance between the fibers of the mesh?	2 3 4 5	go through all of those today, but I did want to show the jury just a couple of your peer-reviewed publications contained in your research on the relationship between inflammation and contraction and adequate mesh pore size for polypropylene meshes.
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Page 50 Page 52 1 O. And in this 2005 article, does it discuss 1 document down there where it says "loose 2 network." 2 your research on inflammation and scarring and its 3 3 BY MR. ANDERSON: relationship to adequate pore size? 4 Q. Doctor, drawing your attention to this part 4 A. Yes. 5 of your peer-reviewed publication from 2002, what 5 MR. ANDERSON: If we go to the second page of 6 does that statement tell us in terms of this 6 the article and we blow up this left side, if you 7 7 relationship between these -- the distance between could draw up some language there and do the 8 the fibers and patient complications? 8 photograph underneath it as well. Thank you, 9 9 A. In this publication from 2002, we described Michael. 10 that we found that if you have larger pores of more 10 BY MR. ANDERSON: 11 than 1, 2 millimeters, then the scar tissue is 11 Q. Explain to the jury if this has any 12 limited to the fibers and that the pores, the holes 12 significance to you in this relationship of pore size 13 13 of a mesh and patient complications. in between the fibers, are filled by fat tissue. So 14 these are the good pores, whereas if you have smaller 14 A. So this manuscript basically is a summary of 15 15 pores, less than 1 millimeter, you usually have scar these ten-year works. 16 16 tissue linking these fibers strongly to each other Q. Ten-year work with Ethicon you mean? 17 17 A. With Ethicon where we wanted to develop safer and making the entire implant stiff and rigid. 18 Q. And just to be clear, Doctor, does that mean 18 meshes together with them. And you see an example of 19 that every pore from an explanted mesh that is less 19 small pore meshes on the left side with the number 20 than 1,000 microns, that every one of them is going 20 "A" there. These are very small pores, and these are 21 21 all filled up by scar tissue, making this rigid mesh to be filled with scar? 22 A. No. But the risk is very, very high that 22 scar compound. 23 23 Q. Well, it's not filled with scar tissue in these pores are filled by scar tissue; and, 24 24 therefore, you have to say, the larger the pore, the this picture. Page 53 Page 51 1 lesser the risk. 1 A. No. These -- these are images from the 2 Q. So the higher the -- the further the distance 2 textile that you're taking out of the box; but if you 3 3 of the fibers above 1,000 microns, the less risk of are placing these meshes into the tissues, then you 4 this bridging of the scar tissue? will find as a result this integration into thick 5 5 A. Yeah, less risk and make it more safer, then, scar tissue, making this small pore net a high risk 6 6 device for -- with a high risk for getting for the patient. 7 Q. Okay. And if we could just turn to the last 7 complications. 8 8 On the right side you see what is possible, page. 9 Who funded this study that you did regarding 9 and that is the development that we, together with 10 impact of polymer pore science? 10 Ethicon, realized, that we enlarged -- we make the 11 A. These findings were part and as a result of 11 pores much larger, up to 3 to 5 millimeters. And if 12 our collaboration in these ten years where we worked 12 you place this textile construction into the tissues 13 together with the people from Ethicon. 13 and then look afterwards what happens, you will find 14 14 a very flexible, thin mesh tissue compound which is 15 15 (Plaintiff's Exhibit No. PLT0271, Article integrated into fat tissue. And, therefore, it is a 16 entitled "The lightweight and large porous concept 16 good example that by reduction of the material to 30 17 17 for hernia repair", was marked for identification.) percent of this of the left side by making the pores 18 18 larger, that you can improve significantly the 19 BY MR. ANDERSON: 19 reaction of their surrounding tissue. 20 Q. I'm now handing you what has been marked as 20 Q. So when you were talking about wanting to 21 Plaintiff's PLT0271. 21 have this good tissue, this fat tissue in the pores 22 Do you recognize this as another one of your 22 or the open spaces, in the figure to the right in B, 23 peer-reviewed publications? 23 would that be the area where it's the open diamond 24 A. Yes. 24 space?

s the area you want the fat tissue to	1 2 3	A. Bridging means that the scar is filling out completely the pores, the room in between the fibers,
		completely the pores, the room in between the fibers,
a wa want ta haya this fat tissua	2	
we went to have this fot tissue	ر ا	which means a risk.
we want to have this fat tissue,	4	Q. A risk what type of risk, Doctor?
fat tissue keeps it flexible,	5	A. A risk for contraction of the scar and the
elastic.	6	mesh and pain and erosion and dysfunction.
	7	Q. As the pore sizes of a mesh in use are
tiff's Exhibit No. P1679, PowerPoint	8	greater than 1 millimeter or 1,000 microns, in your
entitled "Factors related to mesh	9	opinion will that reduce the risk of contraction?
What do we know? A review of literature	10	A. Yes.
	11	Q. And with pore sizes in use that are less than
	12	1,000 microns, or 1 millimeter, in your opinion will
	13	that increase the risk of mesh shrinkage or
NDERSON:	14	contraction?
. I'm going to show you a document,	15	A. Definitely, yes.
	16	MR. THOMAS: Just show my objection to
	17	leading questions.
	18	BY MR. ANDERSON:
	19	O. Go ahead.
- ·	20	A. So definitely. A pore size below
3 1	21	1 millimeter will increase the risk for scar bridging
it is.	22	and will increase the risk for complications.
	23	Q. Dr. Klinge, I now want to talk about another
, ,	24	concept with you, and that's about how and when it is
Page 55		Page 57
Ethicon document showing or dealing	1	important to measure the pores of meshes like
rs related to mesh shrinkage.	2	Prolift. I know that you asked me to bring a
could just turn over, please, to	3	basketball net here today to help provide at least a
is PowerPoint. And what is the date on	4	simple explanation to begin with of the importance of
ft there?	5	the pore measurements; is that correct?
NDERSON: If you could blow that up.	6	A. Yes.
DERSON:	7	MR. ANDERSON: Okay. Just for demonstrative
s the date of this PowerPoint, Doctor?	8	purposes and for the record, we have marked the
one in 2007.	9	basketball net as Plaintiff's Exhibit P3365.
NDERSON: Okay. Take down the blowup.	10	
DERSON:	11	(Plaintiff's Exhibit No. P3365, Basketball
hat do we find from this particular	12	net, was marked for identification.)
	13	
NDERSON: And if you would highlight the	14	MR. ANDERSON: Are you ready? Okay. Thank
t 2 from this Ethicon PowerPoint.	15	you.
ITNESS: The people who made this, they	16	BY MR. ANDERSON:
ge that the pore size has to be more	17	Q. So, Doctor, explain what you're trying to
imeter to avoid this fibrotic bridging	18	show the jury here with regard to pore size and pore
gerous scarring of the holes.	19	measurement.
DERSON:	20	A. So we know that the pore size is critical for
So fibrotic bridging, fibrosis relates	21	the tissue reaction. We want to have large pores.
	22	When you are taking out a net of the box, then the
	23	norse may be sufficient; but if you have it in use
		pores may be sufficient; but if you have it in use,
	What do we know? A review of literature studies", was marked for n.) NDERSON: 7. I'm going to show you a document, whibit P1679. 1've seen it. 1is it something that you saw in this d it is significant to your opinions in it is. 7. And what is this document, if you	What do we know? A review of literature studies", was marked for n.) NDERSON: NDERSON: NDERSON: Nous seen this document before, Doctor? I've seen it. is it something that you saw in this dit is significant to your opinions in it is And what is this document, if you Page 55 Ethicon document showing or dealing or related to mesh shrinkage. Page 55 Ethicon document showing or dealing or related to mesh shrinkage. Pould just turn over, please, to is PowerPoint. And what is the date on fit there? NDERSON: If you could blow that up. DERSON: s the date of this PowerPoint, Doctor? NDERSON: Okay. Take down the blowup. DERSON: hat do we find from this particular NDERSON: And if you would highlight the to 2 from this Ethicon PowerPoint. ITTNESS: The people who made this, they ge that the pore size has to be more imeter to avoid this fibrotic bridging gerous scarring of the holes. DERSON: So fibrotic bridging, fibrosis relates

Page 60 Page 58 machine, the details of it in 2007, and later on some 1 slight forces to it, you see that you have this 1 2 collapse of pores, that even very small pores can get 2 of the results in 2013. 3 3 Q. And do those peer-reviewed publications cover very, very small. And, therefore, by applying these 4 forces to a net, it can make a large pore net to a 4 all of the protocols and the test methods and the 5 small pore net and, thereby, increases the risks 5 setup and analysis of the testing? 6 considerably. 6 A. Yes. In every detail. 7 7 Q. So in your opinion, in terms of patient Q. And did one of those publications actually 8 safety, when is it important to look at the greatest 8 involve testing of the Prolift device on this machine 9 distance between the fibers? Before it goes in the 9 in order to investigate the pores after stretch is 10 body or after? 10 applied? 11 MR. THOMAS: Objection. 11 A. Yes, it is. 12 Q. Or after it's used? 12 Q. And were you involved in the development of 13 MR. THOMAS: Objection; foundation, expertise 13 the testing and the protocols and parameters for the 14 designation. 14 pore testing for that 2013 article looking at the 15 15 BY MR. ANDERSON: Prolift mesh? 16 A. Yes, I was involved in all of this, and I was 16 Q. Go ahead, Doctor. 17 A. You have to take into account that any force 17 the medical doctor who was responsible for the 18 can lead to a pore collapse, and if you want to use a 18 interpretation and analysis of this data. 19 mesh in an area where these forces may occur, then, 19 Q. Did the testing that was published by you in 20 20 of course, you have to analyze the pore size in use. 2013 include testing on the Prolift arms? 21 21 Q. Doctor, did you do testing on the Prolift A. Yes, it did. 22 mesh to determine what would happen to the Prolift 22 23 23 pores when stretch forces are applied, for instance, (Plaintiff's Exhibit No. PLT0697, Article 24 when the Prolift is going to be implanted in a woman? 24 entitled "Elongation of textile pelvic floor implants Page 59 Page 61 1 Did you do testing? 1 under load is related to complete loss of effective 2 A. We did it. 2 porosity, thereby favoring incorporation in scar 3 3 plates", was marked for identification.) Q. Please explain just generally the testing 4 that you were involved in regarding looking at the 4 5 5 pores after forces are applied to them. BY MR. ANDERSON: 6 A. In 2005 I met with a colleague of mine from 6 Q. I'm showing you what has been marked as 7 the technical university, Prof. Dr. Thomas Mühl, and 7 Plaintiff's Exhibit PLT0697. Doctor, is this that 8 8 we wanted to develop a machine that makes it possible 2013 publication regarding your testing of the Prolift device? 9 to really measure pore sizes and to really give a 9 10 10 measurement what happens to the pores when applying A. Yes, it is. 11 some forces to it. We want to have a measurement 11 MR. ANDERSON: If you would hit that. Yeah. 12 12 that is reproducible, that is objective, and that is BY MR. ANDERSON: 13 reliable. And this has not been done before and, 13 Q. And if you could please go with me to page 5. 14 therefore, we developed this machine and finally 14 And we have blown up the left-hand side and have some 15 could finish our work in 2007. 15 images as well as the figure box below that. 16 Q. Was that work published in the peer-reviewed 16 What are we seeing here, Doctor, in terms of 17 17 literature? the testing in this scientific research that you did? 18 18 A. Yes. We publish everything and didn't want A. In the upper part you are just seeing an 19 to restrict it because we -- we want to make it 19 image of the Gynemesh PS or the Prolift mesh without 20 public so that everyone can use this way to optimize 20 applying any tension to it. You see the black lines. 21 21 his research and development. These are the fibers, and the room in between these Q. And when was that information published in 22 22 are the pores. 23 the peer-reviewed literature? 23 Q. And, Doctor, how much force was applied to 24 A. We published this, the technique, the 24 the Prolift arms that we're seeing in this testing

Page 64 Page 62 1 Applicability/Suitability, Bates stamped 1 that was published in 2013? 2 A. So, yeah, I forgot to explain. The lower 2 ETH.MESH.01992234 through ETH.MESH.01992237, was 3 3 image shows the same structure when applying some marked for identification.) 4 force to it. So you see the same change as you see 4 5 with the basketball net. When you apply some forces 5 BY MR. ANDERSON: 6 to it, you find -- you see a collapse of the pores. 6 Q. I'm showing you, Doctor, what the plaintiffs 7 7 The pores -- the force that we applied in this have marked and is noted on the slide as Plaintiff's 8 experiment was 4.9 newton. That is around one pound. 8 0777, is this the document where they estimated 9 9 Q. How did you determine what forces you were approximately 5 pounds of force? going to place on the Prolift arms during this 10 10 A. Yes, it is. 11 testing that's published in 2013? 11 Q. And does 2.3 newtons per centimeter estimate 12 A. We had been looking to the many Ethicon 12 to about 5 pounds of force? 13 internal documents, and we wanted to keep below their 13 A. Yes. 14 limits what they assume to be reasonable limits, and 14 15 we found two references, at least two references. 15 (Plaintiff's Demonstrative Exhibit No. P3357, 16 Q. And when you're saying references, are you 16 Document Bates stamped ETH-01755, was marked for 17 talking about references in the Ethicon documents to 17 identification.) 18 the foreseeable amounts of forces that would be 18 19 placed on the arms during the implantation of the BY MR. ANDERSON: 19 20 Prolift? 20 Q. Okay. And then showing you what has been 21 A. Yes. 21 marked as Plaintiff's Exhibit P3357, is this the 22 22 document that you referenced in terms of Ethicon 23 (Plaintiff's Demonstrative Exhibit No. P3360, 23 stating that you could estimate 12 pounds of force by 24 PowerPoint slide, a blowup referencing PLT0697, 24 the surgeon being placed on the Prolift arms during a Page 63 Page 65 1 "Elongation of textile pelvic floor implants under 1 Prolift procedure? 2 load is related to complete loss of effective 2 A. Exactly. 3 3 porosity, thereby favoring incorporation in scar Q. Okay. Thank you. 4 4 Doctor, what is the significance of your plates", was marked for identification.) 5 5 findings with regard to the mesh that we see that has 6 BY MR. ANDERSON: 6 had 1.1 pounds of force applied to it in terms of the 7 Q. Okay. And we created a slide, I think, to 7 tissue response in the patient? 8 8 help the jury with that demonstrative, Plaintiff's A. It clearly demonstrates and confirms that you 9 Exhibit 3360. 9 have a change of the pore size when applying some 10 MR. ANDERSON: If you could just put in those 10 force to it and that even very low forces can lead to 11 very, very small pore mesh -- meshes; and, therefore, 11 two references. 12 the application of slight forces changing the 12 BY MR. ANDERSON: 13 appearance of a mesh like this will increase risks. 13 Q. And, Doctor, are these the two references 14 Q. Okay. Well, put it simply, what does that 14 from the Ethicon documents regarding two different 15 15 mesh on the bottom mean to the patient? estimated forces that may be placed on the arms? 16 A. Yes. In these two documents you find either 16 MR. THOMAS: Objection; foundation, 17 expertise. 17 5 pounds in the one document or even 12 pounds in the 18 BY MR. ANDERSON: 18 other, and so we wanted to be below this range, not 19 to show that there is a collapse with extremely high 19 Q. Yeah. I think we've laid your foundation for 20 expertise. Go ahead, Doctor. 20 forces, but we want to know what happens to pores 21 A. The mesh will mean increased risk for scar 21 when applying just 1 pound. 22 bridging, shrinkage, contraction, pain, erosion. 22 23 (Plaintiff's Exhibit No. P0777, Ethicon 23 Q. Okay. In your review of the internal Ethicon 24 documents in this case, did you determine whether 24 document, Form for Test Method

	Page 66		Page 68
1	Ethicon's scientists had considered your and	1	Hamburg, Ethicon.
2	Dr. Mühl's pore testing publications and the effects	2	Q. Did you work with him in the last 20 years?
3	of mesh pore size under strain?	3	A. He was a member of the working group that has
4	A. Yes, I did.	4	been working together with us.
5	·	5	Q. And if we see the attachment to this e-mail,
6	(Plaintiff's Exhibit No. P0829, E-mail chain	6	two years later what do you find here, Doctor?
7	and article entitled "New Objective Measurement to	7	MR. THOMAS: Objection; postdates
8	Characterize the Porosity of Textile Implants," Bates	8	Ms. Bellew's surgery, and there is nothing here
9	stamped ETH.MESH.02184130 through ETH.MESH.02184138,	9	to comment on other than the fact it's just a
10	was marked for identification.)	10	transmittal letter.
11	, , , , , , , , , , , , , , , , , , ,	11	BY MR. ANDERSON:
12	BY MR. ANDERSON:	12	Q. Go ahead, Doctor.
13	Q. Let's pull up the two documents so the jury	13	A. In 2010 they again circulated it to the
14	can see what we're talking about.	14	members of their research groups.
15	I'm handing you what has been premarked as	15	
16	Plaintiff's Exhibit P0829. Have you seen this	16	(Plaintiff's Exhibit No. P1087, PowerPoint
17	document before, Dr. Klinge?	17	presentation entitled "Thunder: Technical Review,
18	A. Yes, I've seen.	18	Somerville 28th February 2008", was marked for
19	Q. Is this something you considered and reviewed	19	identification.)
20	in arriving at your opinions in this case?	20	,
21	A. Yes.	21	BY MR. ANDERSON:
22	MR. ANDERSON: If we could blow up the top	22	Q. I'm showing you what has been marked as
23	part of this and also show the attachment that	23	Plaintiff's Exhibit P1087.
24	goes with this article with this internal	24	Have you seen this document before,
	Page 67		
	rage or		Page 69
1	Ethicon e-mail. Yes.	1	Dr. Klinge?
1 2	Ethicon e-mail. Yes. BY MR. ANDERSON:	2	Dr. Klinge? A. Yes, I've seen it.
	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of	2 3	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in
2	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment.	2	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today?
2	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of	2 3 4 5	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is.
2 3 4	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind.	2 3 4 5 6	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document?
2 3 4 5 6 7	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our	2 3 4 5 6 7	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon.
2 3 4 5 6	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a	2 3 4 5 6 7 8	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated?
2 3 4 5 6 7	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they	2 3 4 5 6 7 8	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008.
2 3 4 5 6 7 8 9	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a	2 3 4 5 6 7 8 9	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of
2 3 4 5 6 7 8 9 10	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it.	2 3 4 5 6 7 8 9 10	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the
2 3 4 5 6 7 8 9 10 11	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it.	2 3 4 5 6 7 8 9 10 11	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before?
2 3 4 5 6 7 8 9 10 11 12	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective")	2 3 4 5 6 7 8 9 10 11 12 13	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it.
2 3 4 5 6 7 8 9 10 11 12 13 14	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile	2 3 4 5 6 7 8 9 10 11 12 13 14	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with
2 3 4 5 6 7 8 9 10 11 12 13 14 15	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through	2 3 4 5 6 7 8 9 10 11 12 13 14	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.)	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON:	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON: Q. Okay. Let me show you another document which	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you would like to point out to the jury?
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON: Q. Okay. Let me show you another document which is Plaintiff's Exhibit 1437, which is another e-mail,	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you would like to point out to the jury? MR. ANDERSON: Highlight 4.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON: Q. Okay. Let me show you another document which is Plaintiff's Exhibit 1437, which is another e-mail, an Ethicon e-mail, this one dated 2010, from a	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you would like to point out to the jury? MR. ANDERSON: Highlight 4. A. So in this definition of the requirements to
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON: Q. Okay. Let me show you another document which is Plaintiff's Exhibit 1437, which is another e-mail, an Ethicon e-mail, this one dated 2010, from a Dr. Joerg Holste to a Dr. Juergen Trzewik. Do you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you would like to point out to the jury? MR. ANDERSON: Highlight 4. A. So in this definition of the requirements to improve, as it is said in the subtitle, "Improving
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Ethicon e-mail. Yes. BY MR. ANDERSON: Q. Explain what the significance is to you of this e-mail in 2008 as well as the attachment. MR. THOMAS: Objection; calls for Ethicon's state of mind. THE WITNESS: They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it. (Plaintiff's Exhibit No. P1437, October 7, 2010, e-mail and article entitled "New Objective Measurement to Characterize the Porosity of Textile Implants," Bates stamped ETH.MESH.04945136 through ETH.MESH.04945144, was marked for identification.) BY MR. ANDERSON: Q. Okay. Let me show you another document which is Plaintiff's Exhibit 1437, which is another e-mail, an Ethicon e-mail, this one dated 2010, from a Dr. Joerg Holste to a Dr. Juergen Trzewik. Do you	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Dr. Klinge? A. Yes, I've seen it. Q. And is it significant to your opinions in this case today? A. Yes, it is. Q. And what generally is this document? A. It's a technical review from Ethicon. Q. And what year is this dated? A. It's made from 2008. Q. If you would turn, please, over to page 21 of Plaintiff's Exhibit 1087. Is this slide of the PowerPoint something you've seen before? A. Yes, I've seen it. Q. And is this significant to your opinions with regard to a pore collapse and pore deformation and its relation to patient injury? A. Yeah. Q. Okay. What do you see here, Doctor, that you would like to point out to the jury? MR. ANDERSON: Highlight 4. A. So in this definition of the requirements to improve, as it is said in the subtitle, "Improving

	Page 70		Page 72
1	improve this these results, shrinkage and	1	the force to it.
2	stiffening; and they defined a pore size of more than	2	Q. Thank you, Doctor.
3	3 millimeter as being essential, and for the first	3	
4	time they mentioned a pore size of 1 millimeter under	4	(Plaintiff's Exhibit No. P2995, PowerPoint
5	stretch. So they acknowledged that you have to look	5	presentation entitled "Mesh Properties - How
6	to the pore size and use additionally to the pore	6	important are they?" was marked for identification.)
7	size in the box or without any forces.	7	
8	MR. THOMAS: Objection; move to strike. Goes	8	BY MR. ANDERSON:
9	beyond what the document says.	9	Q. Going I want to show you now Plaintiff's
10	BY MR. ANDERSON:	10	Exhibit P2995. Is this a document that you have
11	Q. I want to go back to a document previously	11	reviewed and relied upon in this litigation?
12	used, which was Plaintiff's Exhibit 1156. We looked	12	A. Yes, I did.
13	at this with the jury a little earlier today, and	13	Q. And what is this, Doctor?
14	MR. THOMAS: Can you give me just a second,	14	A. This is a PowerPoint presentation from
15	please?	15	Ethicon.
16	MR. ANDERSON: Sure.	16	Q. And if we would go to slide 25 of this
17	MR. THOMAS: Thank you. I have it now.	17	presentation by Ethicon.
18	BY MR. ANDERSON:	18	A. Yes.
19	Q. Okay. If you go to page 13 of this 2008	19	Q. Is that significant to your opinions that
20	Ethicon PowerPoint, have you seen this slide before,	20	you're offering here regarding pore size and pore
21	Doctor?	21	deformation after stretch is applied?
22	A. Yes, I've seen it.	22	A. Yes, it is.
23	Q. And is that significant to your opinions in	23	Q. Okay. Please explain for the jury.
24	this case?	24	A. Because this figure wants to express in the
			- 72
	Page 71		Page 73
1	A. Yes.	1	title already that large pores become very small
2	MR. ANDERSON: Okay. Highlight the left-hand	2	under stress, and it was in contrast to the previous
3	side of this picture.	3	one, which was a drawing. It shows that was an
4	BY MR. ANDERSON:	4	Ethicon experiment showing or trying to demonstrate
5	Q. What are we seeing here, Doctor?	5	what happens to the textile structure to the pores
6	A. So in this image you see the same phenomenon	6	when applying a force to it.
7	as we have seen in with the basketball net, that	7	Q. As part of your review of the materials in
8	when applying some forces, the pores collapse and you	8	this case, did you see the Ethicon video of a Prolift
9	will create a small pore mesh.	9	anterior actually being implanted in a woman?
10	Q. We see the word "effective porosity" there.	10	A. Yes, I did.
11	What's that refer to?	11	Q. And is that video significant to your
12	A. Effective porosity, that's exactly the term	12	opinions in this case?
13	that we were able to define with the testing that we	13	A. Yes, it is.
14	do a lot of, Professor Mühl. So they adopted this	14	Q. Okay. I don't want to have to show the jury
15	terminology in	15	the entire video because they may have already seen
16	Q. Just explain that real simply for the jury,	16	it, but did you ask me to create some screenshots
17	what effective pores would be.	17	from that video?
18	A. So effective pores means that is the area of	18	A. Yes.
19	the good pores roughly. So the good pores are those	19	Q. Okay. And did we create a slide showing
	with fat. If you start with half of the pores are	20	these videos
20	C11 11 C	21	A. Yes.
21	filled by fat in the upper line, then it's going to		
21 22	zero in the lower if you applied some force to it.	22	Q these screenshots for the jury?
21		22 23 24	Q these screenshots for the jury?A. Sorry.Q. Sorry. Yes?

1	Page 74		Page 76
	A. Yes.	1	A. Obviously the forces in the OR when in use
2		2	are too high for this specific design of this mesh,
3	(Plaintiff's Demonstrative Exhibit No. P3361,	3	leading to this roping, even in this teaching video.
4	PowerPoint slide entitled "Pores Collapse Under	4	MR. THOMAS: Objection; move to strike,
5	Tension," referencing P2995, ETH.MESH.05237872, PLT	5	beyond the area of expertise and not a disclosed
6	0697, P1452 - ETH.MESH.000007, was marked for	6	opinion.
7	identification.)	7	MR. ANDERSON: It certainly was disclosed
8		8	opinions, and the videos are in his reliance
9	BY MR. ANDERSON:	9	materials. And he talked about initial force, 12
10	Q. Okay. I'll put up this next slide which	10	pounds of force. He talks about 5 pounds of
11	we'll use for demonstrative as P3361. Just one	11	force. He says that when you use the applied
12	second. Go ahead.	12	loads that Ethicon used that you get to see pore
13	MR. THOMAS: Before you show that to the	13	deformation. He said that you see it from
14	jury, are you representing that this is	14	Ethicon's documents, his documents and the DVD.
15	Ms. Bellew's surgery?	15	BY MR. ANDERSON:
16	MR. ANDERSON: If I did, I would have said	16	Q. Okay. So if we can just zoom in on this
17	that.	17	Ethicon DVD on the right-hand side produced by
18	MR. THOMAS: That's why I show my objection	18	Ethicon in this litigation, is that significant to
19	to this not being representative of Ms. Bellew's	19	your opinions? Is that what you were discussing with
20	surgery.	20	the jury of how the mesh is curled and roped and
21	MR. ANDERSON: It's okay. It's your	21	deformed?
22	document.	22	A. Yes.
23	BY MR. ANDERSON:	23	MR. THOMAS: Same objection.
24	Q. So showing you Plaintiff's Exhibit P3361,	24	THE WITNESS: Exactly. So this is not longer
	Page 75		Page 77
1	over to the right is that a screen shot from a DVD	1	any large pore mesh design. This rope will be
2	produced by Ethicon of Ethicon surgeons implanting a		
3		2	integrated into dense scar tissue and nothing
3	Prolift anterior into a woman?	3	integrated into dense scar tissue and nothing nothing else, and it will become stiff and rigid.
4	Prolift anterior into a woman? A. Yes.		
		3	nothing else, and it will become stiff and rigid.
4	A. Yes.	3 4	nothing else, and it will become stiff and rigid. BY MR. ANDERSON:
4 5	A. Yes.Q. Okay. So you asked me to put these three	3 4 5	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is
4 5 6	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why	3 4 5 6	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the
4 5 6 7	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see,	3 4 5 6 7	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not. MR. ANDERSON: Okay. You can take that down.
4 5 6 7 8	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor? A. Because it makes very clear that we have to deal with a realistic problem. On the left you see	3 4 5 6 7 8	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not.
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4 5 6 7 8 9 10 11 12	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor? A. Because it makes very clear that we have to deal with a realistic problem. On the left you see the image from the Ethicon study where they just described it. In the middle you see an image of our testing	3 4 5 6 7 8 9 10 11 12 13	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not. MR. ANDERSON: Okay. You can take that down. Oh, actually, bring that back up. BY MR. ANDERSON: Q. Do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the
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4 5 6 7 8 9 10 11 12 13 14 15 16 17	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor? A. Because it makes very clear that we have to deal with a realistic problem. On the left you see the image from the Ethicon study where they just described it. In the middle you see an image of our testing where we tried to measure it to quantify the consequences to different forces. And on the right you see exactly the same deformation, the same roping of the arms during the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not. MR. ANDERSON: Okay. You can take that down. Oh, actually, bring that back up. BY MR. ANDERSON: Q. Do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the mesh arms that the jury is seeing in the right-hand picture would result in unnecessary risk to the tissues? MR. THOMAS: Objection; beyond his area of
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4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor? A. Because it makes very clear that we have to deal with a realistic problem. On the left you see the image from the Ethicon study where they just described it. In the middle you see an image of our testing where we tried to measure it to quantify the consequences to different forces. And on the right you see exactly the same deformation, the same roping of the arms during the OR. So the collapse of pores is a real phenomenon. Q. So whether we can take the Ethicon document that says 5 pounds of force is placed by the surgeon on the arms during implant or 12 pounds of force	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not. MR. ANDERSON: Okay. You can take that down. Oh, actually, bring that back up. BY MR. ANDERSON: Q. Do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the mesh arms that the jury is seeing in the right-hand picture would result in unnecessary risk to the tissues? MR. THOMAS: Objection; beyond his area of expertise. THE WITNESS: The appearance of such a mesh in this roping form means a considerable risk, and because it is there is no need for this,
4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Okay. So you asked me to put these three images together. Why did you ask me to do that? Why do you think that's important for the jury to see, Doctor? A. Because it makes very clear that we have to deal with a realistic problem. On the left you see the image from the Ethicon study where they just described it. In the middle you see an image of our testing where we tried to measure it to quantify the consequences to different forces. And on the right you see exactly the same deformation, the same roping of the arms during the OR. So the collapse of pores is a real phenomenon. Q. So whether we can take the Ethicon document that says 5 pounds of force is placed by the surgeon on the arms during implant or 12 pounds of force during implant, this image to the right, is this the	3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	nothing else, and it will become stiff and rigid. BY MR. ANDERSON: Q. Is that appearance of the arm right there, is that what it looks like when it comes out of the Ethicon box? A. No, definitely not. MR. ANDERSON: Okay. You can take that down. Oh, actually, bring that back up. BY MR. ANDERSON: Q. Do you have an opinion to a reasonable degree of medical and scientific certainty as to whether the mesh arms that the jury is seeing in the right-hand picture would result in unnecessary risk to the tissues? MR. THOMAS: Objection; beyond his area of expertise. THE WITNESS: The appearance of such a mesh in this roping form means a considerable risk, and because it is there is no need for this, it is an unnecessary risk.

tissue rissponse, would that risk be the same with abdominal tissue, the pelvic tissue or the tissue under your armpit? M. R. THOMAS: Same objection. THE WITHSES: A mesh curted like this, getting these small pores like this one will result everywhere in the body in a scar mesh compound that is stiff and rigid and not flexible any longer. M. R. ANDERSON: M. A. ANDERSON: M. R. ANDERSON: M. A.		Page 78		Page 80
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	Page 82		Page 84
1	Q. Now go.	1	you were a practicing surgeon with a focus on
2	A. Because it carries unnecessary risk. It is	2	abdominal hernia repairs; correct?
3	designed unsafe and defective.	3	A. No. Ah.
4	MR. ANDERSON: Thank you. No further	4	Q. What?
5	questions at this time.	5	A. Yeah. So I just understand. I was an
6	THE VIDEOGRAPHER: We are off the record.	6	abdominal surgeon with the focus on hernia surgery.
7	The time is 10:22 a.m.	7	That is okay, yeah.
8	(A recess was taken from 10:22 a.m. until 10:33 a.m.)	8	Q. Okay. Fine. Thank you.
9	THE VIDEOGRAPHER: This marks beginning of	9	And I'm not trying to trick you. If you
10	Video Number 2. We are back on the record. The	10	don't understand my question, let me know, and I'll
11	time is 10:33 a.m.	11	try to rephrase it. I know that English is not your
12	CROSS-EXAMINATION	12	first language, and I'll do the first I can.
13	BY MR. THOMAS:	13	A. And I am not sure every time.
14	Q. Good morning, Dr. Klinge.	14	Q. And I speak West Virginian. I don't speak
15	A. Good morning.	15	German.
16	Q. You're an expert that's been retained by	16	Doctor, you've not performed surgery since
17	Mr. Anderson in this case; is that correct? Expert	17	2006, have you?
18	witness?	18	A. Not in humans.
19	A. Yes.	19	Q. Okay. And prior to 2006, you treated
20	Q. And you're paid for the time that you spend	20	hernias?
21	working on this matter?	21	A. Yes.
22	A. Yes.	22	Q. And a hernia is essentially an organ pushing
23	Q. And you're paid at the rate of \$500 an hour;	23	through the abdominal wall; correct?
24	is that right?	24	A. Not always.
	Page 83		Page 85
1	A. Yes.	1	Q. Why can you not describe a hernia as an organ
2	Q. How much money have you been paid to work on	2	pushing through the abdominal wall?
3	this case?	3	A. Because there are hernias, for example, close
4	MR. ANDERSON: Objection. You mean Bellew?	4	to the esophagus, through the diaphragm, where you
5	MR. THOMAS: Yes.	5	have a hernia, but it is not a defect in the
6	MR. ANDERSON: The Bellew case.	6	abdominal wall.
7	THE WITNESS: It's about \$20,000, included	7	Q. Okay. Well, you could repair hernias with
8	the tax. In Germany you have to reduce it almost	8	sutures; is that correct?
9	by half.	9	A. You can try to repair it by sutures, yes.
10	BY MR. THOMAS:	10	Q. And sutures are sometimes called stitches?
11	Q. Okay. And in preparation for your deposition	11	A. Yes.
12	today, you met with Mr. Anderson?	12	Q. And sutures and stitches are the Prolene that
13	A. Yes.	13	you showed to the jury on direct examination;
14	Q. And how many days did you meet with	14	correct?
15	Mr. Anderson?	15	A. There are many kind of different sutures,
16	A. Three days.	16	different suture materials, and one of the suture
17	Q. Okay. And how many hours did you spend with	17	material is Prolene.
18	Mr. Anderson in preparation for your deposition?	18	Q. And when you repair a hernia with sutures,
19	A. Six hours a day.	19	you basically put the tissue back in place and then
20	Q. So about 18 hours?	20	support it with the stitches; correct?
	A. Maybe.	21	A. The stitches are supported to keep the
	Q. So about \$9,000; correct?	22	approximation of the tissues together, yeah.
21 22		1	approximation of the tipodes together, your.
22		23	O. Okay. And you can also treat hernias with
	A. Yeah. Q. All right. Now, from the mid-1990s to 2006,	23 24	Q. Okay. And you can also treat hernias with surgical mesh; correct?

	Page 86		Page 88
1	A. Yes.	1	Q. And we don't have a Prolift here, but the
2	Q. And you can repair hernias with polypropylene	2	Prolift itself does not look like Exhibit 3364;
3	mesh; correct?	3	correct?
4	A. Yes.	4	A. Yes.
5	Q. There are about 20 million surgical mesh	5	Q. Now, the hernia meshes that you used to
6	implantations every year; true?	6	repair hernias are often bigger than the meshes used
7	A. That is said by Saunders in his reference.	7	in the pelvic floor to repair a pelvic organ
8	Whether it's true, I didn't count it.	8	prolapse; correct?
9	Q. And abdominal hernia repair is the most	9	A. The meshes can be bigger, but the area for
10	frequently performed operation and surgery; correct?	10	implantation is completely different.
11	A. That is correct.	11	Q. So are you telling the jury that implanting a
12	Q. And the use of mesh to repair hernias is an	12	mesh in the abdominal area is different from
13	important option for patients; true?	13	implanting a mesh in the pelvic floor?
14	A. Yes.	14	MR. ANDERSON: Objection.
15	Q. Polypropylene is the most widely used mesh	15	THE WITNESS: Yes.
16	for hernia repair; true?	16	MR. ANDERSON: Go ahead.
17	A. That should be true.	17	BY MR. THOMAS:
18	Q. And mesh implants made of polypropylene have	18	Q. Stay with me, though, for a minute. But the
19	been used in the human body since 1963; true?	19	amount of mesh that you implant in the abdominal area
20	A. That is true.	20	to repair hernias is often much more than the amount
21	Q. And Ethicon began selling Prolene mesh for	21	of mesh that's used in this anterior Prolift that you
22	hernia repair in 1974?	22	have described in P3364; correct?
23	A. Yeah.	23	A. It was correct before we developed together
24	Q. And the Prolene mesh that's used to repair	24	with Ethicon these large pore meshes, which have a
	Da 07		Page 20
	Page 87		Page 89
1	hernias is the same material that is used to make	1	reduced amount of material. We could reduce the
2	Prolene soft in the Prolift; correct?	2	amount of polypropylene to 30 percent of these
3	A. Please, can you	3	heavyweight small pore meshes, and, therefore, it is
4	Q. Prolene mesh used in hernia repair is made of	4	difficult. It depends from from the specific size
5	the same polypropylene material that is used to make Prolene soft for use in the Prolift?	5	of the mesh. Then you can do this calculation and
6		6	look whether it exactly fits or whether it's a little
7	A. I think so, yeah.	7	bit more.
8	Q. Now, you started implanting polypropylene	8	Q. Meshes that you used before 2006 to implant
9	mesh for hernia repair in the early 1990s; true?	9	into humans for the repair of hernias had more
10	A. Yes.	10	polypropylene in them than the polypropylene that you
11	Q. And you performed about 200 hernia repairs	11	showed the jury in 3364; correct?
12	using mesh; correct?	12	A. 2006 you said? Q. Before 2006. You implanted meshes
1 2	A Vac		
13	A. Yes.	13	•
14	Q. Now, a minute ago you showed the jury	14	A. We
14 15	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of	14 15	A. We Q some meshes that had more polypropylene
14 15 16	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would	14 15 16	A. We Q some meshes that had more polypropylene than is present in 3364.
14 15 16 17	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct?	14 15 16 17	A. WeQ some meshes that had more polypropylenethan is present in 3364.A. After our development of Vypro of these large
14 15 16 17 18	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes.	14 15 16 17 18	 A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these
14 15 16 17 18	 Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes. Q. Well, just so it's clear, you never implant 	14 15 16 17 18 19	A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of
14 15 16 17 18 19	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes. Q. Well, just so it's clear, you never implant polypropylene in that form into a body, do you?	14 15 16 17 18 19 20	A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of this huge amount of material was very, very rare.
14 15 16 17 18 19 20	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes. Q. Well, just so it's clear, you never implant polypropylene in that form into a body, do you? A. No.	14 15 16 17 18 19 20 21	A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of this huge amount of material was very, very rare. Q. You know today that mesh is used in the
14 15 16 17 18 19 20 21	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes. Q. Well, just so it's clear, you never implant polypropylene in that form into a body, do you? A. No. Q. The polypropylene is woven or knitted into a	14 15 16 17 18 19 20 21 22	A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of this huge amount of material was very, very rare. Q. You know today that mesh is used in the repair of hernias by a doctor every single day, in
14 15 16 17 18 19 20	Q. Now, a minute ago you showed the jury Plaintiff's Exhibit 3364, which is the amount of polypropylene that, if taken apart, the Prolift would have in it; correct? A. Yes. Q. Well, just so it's clear, you never implant polypropylene in that form into a body, do you? A. No.	14 15 16 17 18 19 20 21	A. We Q some meshes that had more polypropylene than is present in 3364. A. After our development of Vypro of these large pore meshes with Ethicon, we only use these material-reduced methods; and, therefore, the use of this huge amount of material was very, very rare. Q. You know today that mesh is used in the

1	Page 90		Page 92
1	don't you?	1	Q. Turn to page 89 of the deposition, please.
2	A. I know that in Germany 90 percent more	2	MR. ANDERSON: I think you gave me two
3	than 90 percent of the meshes used for hernia repair	3	copies, Counsel. Yeah. You gave me
4	are large pore meshes.	4	MR. THOMAS: I think there's two days.
5	Q. And what meshes are those specifically?	5	MR. ANDERSON: Oh, you're going to need both.
6	A. These are Ultrapro. Ultrapro is the leading	6	THE WITNESS: 98?
7	from Ethicon.	7	BY MR. THOMAS:
8	Q. Okay. Are you saying Ultrapro is appropriate	8	Q. Page 89, line 16. You there?
9	for the pelvic floor?	9	"QUESTION: And, Doctor, in the early '90s
10	A. No.	10	the physicians didn't understand all of the
11	Q. So just so your testimony is clear, it's not	11	biomechanical demands of the abdomen; is that
12	your opinion that Ultrapro is an appropriate mesh to	12	correct?
13	treat pelvic organ prolapse in the pelvic floor;	13	"ANSWER: There was limited knowledge about
14	true?	14	the biomechanics of the abdomen."
15	A. If you stick to the third point we presented	15	Did I read that correctly?
16	there, that it has to prevent a pore collapse and	16	MR. ANDERSON: Excuse me. I will object.
17	Ultrapro obviously does not prevent a pore collapse	17	That is not the same question you asked. You
18	when applied to forces; therefore, it is not the best	18	asked, "Do you know everything," and here you
19	idea to use Ultrapro in this for this indication,	19	changed the question from this to what it was in
20	yes.	20	the deposition. So if we were at sidebar, I
21	Q. It's true that you do not have the opinion	21	would have pointed that out to the judge.
22	that Ultrapro is a reasonable alternative design for	22	MR. THOMAS: And I understand your objection.
23	the use of mesh in the treatment of pelvic organ	23	BY MR. THOMAS:
24	prolapse; true?	24	Q. Did I read that correctly?
	Page 91		Page 93
1	MR. ANDERSON: Objection to form.	1	A. Yeah.
2	THE WITNESS: As it carries unnecessary risk,	2	Q. Okay.
3	I am sure that it is not a safe alternative.	3	MR. ANDERSON: It's an inappropriate use of
4	BY MR. THOMAS:	4	the deposition, so that's my objection.
5	Q. Okay. Now, when you started implanting mesh	5	MR. THOMAS: And you stated it clearly.
6	for hernia repair, you didn't understand all of the	6	BY MR. THOMAS:
7	biomechanical demands of the abdomen; true?	7	Q. And, Doctor, it's clear that in the '90s
8	A. It is a permanent learning that I have when I	8	physicians didn't understand all of the biomechanical
9	started surgery. I don't know, but I permanently	9	demands of the abdomen; true?
10	learned about it. And we learned a lot about these	10	A. There was limited knowledge about the
11	meshes, and, of course, when we started to make this	11	biomechanics of the abdomen. Still open questions.
12	research, we didn't know everything.	12	Q. Okay. And when you were performing hernia
13	Q. Are you able to answer my question yes or no?	13	surgery, it was important for you that the patient
14	Let me ask it again.	14	understand whether the benefits of that hernia
15	When you started implanting mesh for hernia	15	surgery outweighed the risks of that hernia surgery;
16	repair, you didn't understand all of the	16	correct?
17	biomechanical demands of the abdomen; true?	17	A. That is correct.
18	A. What do you think of "all"?	18	Q. And it's your job as a doctor to explain the
19	Q. Doctor, let me hand you your deposition that	19	risks of hernia surgery to the patient so the patient
20	you gave.	20	can make that informed decision; correct?
21	I'm sorry. It's the wrong one.	21	A. Yes.
	NY Y 11.	22	Q. And it's true, Doctor, that any surgery has
22	No. I was right.	44	Q. And it's true, Doctor, that any surgery has
	No. 1 was right. MR. ANDERSON: Thank you, Counsel.	23	risks?

	Page 94		Page 96
1	Q. Well, is it true that every hernia surgery	1	A. This topic surely is mentioned with the
2	has risks?	2	patient, that chronic pain may be a serious
3	A. Has some risks.	3	complication after operation, yes.
4	Q. And it's your job to tell a patient about	4	Q. And when you say late onset, that means that
5	those risks so that they can make a decision about	5	this pain does not manifest itself until after the
6	whether to have the surgery; correct?	6	surgery sometime; correct?
7	A. I have to tell him not that there are	7	A. Yes.
8	possible ways to get some complication, but I have to	8	Q. And you also tell patients that hernia mesh
9	give him the information that he gets a good estimate	9	is difficult to remove; true?
10	how big the risk is, whether there is an alternative	10	A. Yes.
11	with a less risk and what is the benefit.	11	Q. And you talk to a patient about a risk of
12	Q. And	12	hernia recurrence?
13	A. So is it a necessary risk or is it an	13	A. Yes.
14	unnecessary risk? And all this together I have to	14	Q. And a hernia recurrence means that the mesh
15	discuss with the patient. It is not so simple to say	15	repair did not work and the hernia repair comes back;
16	there are some risks.	16	correct excuse me, the hernia comes back; is that
17	Q. And you tell the patient that there is a	17	correct?
18	lifelong risk of infection from that mesh implant,	18	A. There are different definitions of
19	wouldn't you?	19	recurrence, and where the hernia comes back, whether
20	A. From the moment we know there is a that we	20	it's really a problem that the mesh doesn't work,
21	learn that there was this permanent inflammation that	21	whether it's a new hernia that is for the patient a
22	you have a lifelong risk for infection. You have an	22	recurrence. So it is not so simple, but we are
23	implant. They received an implant. It's not a	23	discussing the manifestation of another hernia
24	tissue repair. They received a plastic implant for	24	despite using a mesh.
	Page 95		Page 97
1	the rest of their lives.	1	Q. And a patient needs to know that there's a
2	Q. And anytime you have a plastic implant,	2	risk that the surgery won't work; correct?
3	there's a risk, a lifelong risk of an infection;	3	A. Yes.
4	true?	4	Q. And you talk to a patient who is looking at a
5	A. Yes.	5	potential hernia repair with mesh about the risk of
6	Q. And that would be for a hip or for a knee	6	mesh shrinkage; correct?
7	just as well as a mesh; correct?	7	A. Yes.
8	A. But the numbers are different, and it is	8	Q. And any mesh will have a shrinkage or
			Q. And any mesh will have a shrinkage of
9	different to treat it.	9	contracture rate of at least 20 percent; correct?
9 10	different to treat it. Q. Answer to my Doctor, it's fair to say that		
		9	contracture rate of at least 20 percent; correct?
10	Q. Answer to my Doctor, it's fair to say that	9	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the
10 11	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just	9 10 11	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one.
10 11 12	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip	9 10 11 12	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh
10 11 12 13	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no.	9 10 11 12 13	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least
10 11 12 13 14	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of	9 10 11 12 13 14	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct?
10 11 12 13 14	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct.	9 10 11 12 13 14 15	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a
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10 11 12 13 14 15 16	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct. THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get	9 10 11 12 13 14 15 16 17	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent.
10 11 12 13 14 15 16 17	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct. THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get an infection, yes.	9 10 11 12 13 14 15 16 17	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent. Q. And when you were treating patients for
10 11 12 13 14 15 16 17 18	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct. THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get an infection, yes. BY MR. THOMAS:	9 10 11 12 13 14 15 16 17 18	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent. Q. And when you were treating patients for hernia repairs, you explained all of these risks to
10 11 12 13 14 15 16 17 18 19	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct. THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get an infection, yes. BY MR. THOMAS: Q. Thank you.	9 10 11 12 13 14 15 16 17 18 19 20	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent. Q. And when you were treating patients for hernia repairs, you explained all of these risks to the patient so the patient would understand?
10 11 12 13 14 15 16 17 18 19 20 21	Q. Answer to my Doctor, it's fair to say that there's a lifelong risk of infection from mesh, just like there's a lifelong risk of infection from a hip implant or a knee implant? Yes or no. MR. ANDERSON: Objection; beyond the scope of cross beyond the scope of direct. THE WITNESS: If you are thinking of the principal possibility of a lifelong risk to get an infection, yes. BY MR. THOMAS: Q. Thank you. And when you're talking to a patient about	9 10 11 12 13 14 15 16 17 18 19 20 21	contracture rate of at least 20 percent; correct? A. At least 20 percent? The difference is the extent of this one. Q. Any any mesh it's true that any mesh will have a shrinkage or contracture rate of at least 20 percent; correct? A. There may be some conditions where it's a little bit lower, but, yeah, sure, more or less it is. You have to assume a contraction of 20 percent. Q. And when you were treating patients for hernia repairs, you explained all of these risks to the patient so the patient would understand? A. But in a completely different way.

	Page 98		Page 100
1	hernia repair, you believed that the benefits of that	1	A. Yes.
2	mesh outweighed any risks to your patient; true?	2	Q. And the top left-hand corner, is that the
3	A. In some specific patients in some specific	3	area of mesh that you were describing in your direct
4	conditions where we are discussing the alternatives,	4	examination?
5	we are discussing the risks of the patient's	5	A. Yes.
6	conditions, the risk of the procedure, the risk of	6	Q. And that mesh has is covered with tissue;
7	the biomaterials, all this together will end up in	7	correct?
8	the risk-benefit ratio. And when you have all this	8	A. Yes.
9	information, how often something occurs, then you can	9	Q. And that mesh has been stored in
10	discuss it with the patient and you can make your	10	formaldehyde; correct?
11	decision, yes.	11	A. Yes.
12	Q. Well, when you recommended mesh to a patient	12	Q. And you have not measured that mesh to
13	for the repair of their hernia, you believed that the	13	determine the extent to which any pores in that mesh
14	mesh that you were going to use, the benefits of that	14	have collapsed, have you?
15	mesh outweighed the risk to the patients; true?	15	A. Not specifically this mesh.
16	A. In those patients where I am using meshes, I	16	Q. Thank you.
17	have been using meshes, the decision of me and the	17	As a matter of fact, you have not performed
18	patient was that in this case the use of a specific	18	any analysis on the mesh specific to Ms. Bellew;
19	mesh in a specific way outweighs the risks.	19	correct?
20	Q. Okay. Now, over the last 20 years, there are	20	A. Specifically, yeah.
21	millions of people on earth walking around with mesh	21	Q. Now, you have not ever performed surgery for
22	in their body, and a large percentage of those meshes	22	the repair of pelvic organ prolapse; correct?
23	are either polypropylene or they contain	23	A. That is correct.
24	polypropylene; true?	24	Q. And we talked about the Prolift before.
	Page 99		Page 101
1	A. Sure.	1	
2		I	You've never used a Prolift in any surgery; correct?
_	Q. Yeah. Now, you've never treated the	2	You've never used a Prolift in any surgery; correct? A. That is correct.
3	Q. Yeah. Now, you've never treated the plaintiff in this case; correct?		A. That is correct.
		2	
3	plaintiff in this case; correct?	2	A. That is correct.Q. And do you know the tools that are used to
3 4	plaintiff in this case; correct? A. That is correct.	2 3 4	A. That is correct.Q. And do you know the tools that are used to place Prolift?
3 4 5	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in	2 3 4 5	A. That is correct.Q. And do you know the tools that are used to place Prolift?A. I've seen it on the video.
3 4 5 6	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct?	2 3 4 5 6	A. That is correct.Q. And do you know the tools that are used to place Prolift?A. I've seen it on the video.Q. There's a trocar?
3 4 5 6 7	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct.	2 3 4 5 6 7	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes.
3 4 5 6 7 8	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct. Q. And you have never rendered any medical	2 3 4 5 6 7 8	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes. Q. And there's a cannula; correct?
3 4 5 6 7 8 9	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct. Q. And you have never rendered any medical diagnosis specific to the plaintiff in this case;	2 3 4 5 6 7 8	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes. Q. And there's a cannula; correct? A. Yes.
3 4 5 6 7 8 9	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct. Q. And you have never rendered any medical diagnosis specific to the plaintiff in this case; correct?	2 3 4 5 6 7 8 9	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes. Q. And there's a cannula; correct? A. Yes. Q. You've never placed a mesh with trocars, have
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3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct. Q. And you have never rendered any medical diagnosis specific to the plaintiff in this case; correct? A. That is correct. Q. And you have never examined the actual mesh explanted from the plaintiff in this case; correct? Other than the photograph you looked at? A. I think so, yeah. Q. Now, I want to look at that photograph that Mr. Anderson showed you. Do you have it in front of you? Exhibit P3356. Do you have that, Dr. Klinge? A. Yes.	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes. Q. And there's a cannula; correct? A. Yes. Q. You've never placed a mesh with trocars, have you? A. No. Q. You've never placed a mesh with cannulas, have you? A. No. Q. You've never placed a mesh using the same tools as Prolift; correct? A. That is correct. Q. Now, you were shown Exhibit 3361. Could you get that in front of you, please.
3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	plaintiff in this case; correct? A. That is correct. Q. And you've never examined the plaintiff in this case; correct? A. That is correct. Q. And you have never rendered any medical diagnosis specific to the plaintiff in this case; correct? A. That is correct. Q. And you have never examined the actual mesh explanted from the plaintiff in this case; correct? Other than the photograph you looked at? A. I think so, yeah. Q. Now, I want to look at that photograph that Mr. Anderson showed you. Do you have it in front of you? Exhibit P3356. Do you have that, Dr. Klinge? A. Yes. Q. Now	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	 A. That is correct. Q. And do you know the tools that are used to place Prolift? A. I've seen it on the video. Q. There's a trocar? A. Yes. Q. And there's a cannula; correct? A. Yes. Q. You've never placed a mesh with trocars, have you? A. No. Q. You've never placed a mesh with cannulas, have you? A. No. Q. You've never placed a mesh using the same tools as Prolift; correct? A. That is correct. Q. Now, you were shown Exhibit 3361. Could you get that in front of you, please. MR. THOMAS: Could you pull that up, please,

26 (Pages 98 to 101)

	Page 102		Page 104
1	on direct examination, and this is a surgical	1	able to investigate, we saw this deformation, this
2	procedure involving the Prolift; correct?	2	roping in all of these explants, wherever they were
3	A. Yes.	3	taken. It's not a phenomenon that is outside the
4	Q. And it uses cannulas; correct?	4	body. It's inside the body.
5	A. Yes.	5	Q. You've not seen it yourself, have you,
6	Q. And it uses trocars; correct?	6	Doctor?
7	A. Yes.	7	A. In this case, not.
8	Q. And you've never used either one of those;	8	Q. Okay.
9	correct?	9	A. Only in the video I've seen it.
10	A. Yes.	10	Q. And the only video that you've seen of a
11	Q. And you understand that the mesh is to be	11	Prolift repair is the one that you just discussed;
12	placed tension-free inside the body; correct?	12	correct?
13	A. What do you mean by is said or	13	A. That is a video made by Ethicon
14	Q. Do you know that do you know that a	14	Q. Okay.
15	surgeon is to place the Prolift in the body	15	A as a teaching video.
16	tension-free? Do you know that?	16	Q. And you don't have any basis to give an
17	A. There are some ideas that it should be done	17	opinion as to what the mesh looks like in the body,
18	tension-free, but obviously it is not possible to	18	do you?
19	place it tension-free; therefore, there is no	19	MR. ANDERSON: Objection.
20	measurement that it is done tension-free. There	20	THE WITNESS: If you
21	is it's not a fact.	21	BY MR. THOMAS:
22	Q. But you have not done one; correct?	22	Q. Is that yes or no? You can tell me yes or no
23	A. Yes.	23	and then tell me what it is.
24	Q. It's correct that you have not done one?	24	A. Please then.
	Page 103		Page 105
1	A. It is correct that I never did it.	1	Page 105 Q. Do you have any basis to understand what the
1 2		1 2	
	A. It is correct that I never did it.		Q. Do you have any basis to understand what the
2	A. It is correct that I never did it.Q. Okay. You've never tried to place mesh	2	Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted?
2	A. It is correct that I never did it.Q. Okay. You've never tried to place mesh tension-free inside a woman; correct?	2	Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted?A. I have a basis, yes.
2 3 4	A. It is correct that I never did it.Q. Okay. You've never tried to place mesh tension-free inside a woman; correct?A. I the abdominal wall surgery, the use of	2 3 4	Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted?A. I have a basis, yes.Q. And what is that?
2 3 4 5	A. It is correct that I never did it. Q. Okay. You've never tried to place mesh tension-free inside a woman; correct? A. I the abdominal wall surgery, the use of meshes, is supposed to be in a tension-free area. We	2 3 4 5	Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted?A. I have a basis, yes.Q. And what is that?A. This basis is our explants, our the
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. It is correct that I never did it. Q. Okay. You've never tried to place mesh tension-free inside a woman; correct? A. I the abdominal wall surgery, the use of meshes, is supposed to be in a tension-free area. We know that's and I did it in woman. Q. Okay. But not in a pelvic floor? A. Not in the pelvic floor. Q. Okay. And when the Prolift is placed, it goes through cannulas; correct? A. Yes. Q. And that allows for the smooth passage of the mesh through the cannulas; correct? A. It is supposed that you need some forces, according to the internal documents from Ethicon. It is supposed that you need some forces to do so. Q. And you don't know what this mesh looks like inside of the person on whom this surgery is being performed, do you? A. In the video you have it a view from inside, and it appears though the quality is not very good for these slides, but it appears as if	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	Q. Do you have any basis to understand what the mesh looks like in the body after it's implanted? A. I have a basis, yes. Q. And what is that? A. This basis is our explants, our the visualization of many operations that have been shown on the conference where you see it that is the appearance of the arms for Prolift total, Prolift posterior. When you're looking to all of these teaching videos, you always will see that the mesh is not longer laying there in a flat way, but they showed this roping. You can find it almost every in every video and every transmission of an operation. Q. On the outside? A. No. Before sometimes you are able to see the arms before closing all wounds, or sometimes you may make some laparoscopy looking from inside. Q. Now, you're not an expert in pelvic floor surgery with regards to the surgical procedure used to treat pelvic organ prolapse; true? A. In regard to surgical procedure, it's true.

1 2 3 4 5	A. That is true.Q. And you've never consulted with Ethicon on	1	"QUESTION: You've not studied the pelvic
3 4 5	Q. And you've never consulted with Ethicon on		
4 5		2	floor forces in a human; correct?
5	issues of pelvic organ prolapse; true?	3	"ANSWER: That is correct."
	A. That is true.	4	Did I read that correctly?
_	Q. Now, you're not an obstetrician; true?	5	A. Yes.
6	A. Please, what?	6	Q. Thank you.
7	Q. You're not an obstetrician?	7	Now, you agree that mesh is an important
8	A. What is an obste	8	option for patients in pelvic floor repair; correct?
9	Q. Baby doctor.	9	A. In some patients, yes.
10	A. No, I'm not a baby doctor.	10	Q. And you agree that polypropylene is an
11	Q. You're not an obstetrician?	11	appropriate use in pelvic floor if you have the right
12	A. Okay. Yeah. Yeah.	12	construction of that polypropylene; correct?
13	Q. You're not a gynecologist?	13	A. If it's a right construction for this
14	A. I'm not.	14	specific purpose, yeah, it can be.
15	Q. You're not a urologist?	15	Q. Okay. And 91 percent of all gynecological
16	A. I'm not.	16	nonabsorbable meshes are polypropylene; correct?
17	Q. And you're not a urogynecologist; correct?	17	A. It should be, correct. We never I never
18	A. I'm not.	18	analyzed or counted it.
19	Q. And you've never completed a fellowship or	19	Q. Now, over the years you talked about your
20	residency in those fields; correct?	20	work from Ethicon. Ethicon paid you for your work,
21	A. That is correct.	21	didn't they?
22	Q. And you have never studied the pelvic	22	A. In the years from 2000 to 2005, yes. In the
23	forces pelvic floor forces in a human; correct?	23	years before, no.
24	A. We tried. We tried in some research projects	24	Q. And you received royalties from Ethicon for
	Page 107		Page 109
1	to define the or to learn about the anatomy and	1	sales of Vypro; correct?
2	the forces.	2	A. In these this is the payment you're
3	Q. But you did you ever complete the study of	3	talking of. This is in the years from 2000 until
4	pelvic forces in the human?	4	2005. I got something like royalties for the selling
5	A. We completed some of the studies, and I guess	5	of Vypro and Ultrapro.
6	some of this already has been published in a	6	Q. And so every time Ethicon sold a Vypro and an
7	peer-reviewed literature, but of course we are not	7	Ultrapro, you earned money; correct?
8	finished with all our studies in this field.	8	A. Yes.
9	Q. Let me show you another transcript of	9	Q. You earned about 20,000€ a year from
10	testimony, please, and direct your attention to page	10	royalties from Ethicon from 2000 to 2005; is that
11	3497.	11	correct?
12	A. 47?	12	A. That is correct.
13	Q. 3497, line 15.	13	Q. Now, you received no royalties for the sales
14	A. 3497.	14	of Prolene mesh; correct? Prolene Soft Mesh.
15	MR. ANDERSON: And I'll just place an	15	A. Yes.
16	objection on the record. This is outside the	16	Q. I want to go back to another exhibit that you
17	scope of direct. Didn't talk about pelvic	17	talked about on direct, and it's Plaintiff's Exhibit
18	forces.	18	0697. Do you have that?
19	What's your page?	19	A. Not yet.
20	MR. THOMAS: 3497.	20	Q. 0697 is your 2013 study.
21	BY MR. THOMAS:	21	Do you have that now?
22	Q. Do you have it, Doctor?	22	A. Yes.
	A. Yes.	23	Q. And Plaintiff's Exhibit 0697 was published in
23			

28 (Pages 106 to 109)

	Page 110		Page 112
1	A. Yes.	1	Gynemesh PS from polypropylene to a DynaMesh made of
2	Q. Now, in this study in 2013, you compare	2	PVDF in this specific two specific meshes.
3	Prolift and Prolift+M with DynaMesh; correct?	3	Q. And just so the jury understands, DynaMesh is
4	A. That is correct.	4	manufactured by FEG; correct?
5	Q. And you and Mr. Mühl tested this these	5	A. Yes.
6	meshes on the same machine that you conducted your	6	Q. And you, at the time of this study, were a
7	test back in 2007; correct?	7	paid consultant for FEG; correct?
8	A. Yes.	8	A. Yes.
9	Q. And the machine that you developed in 2007	9	Q. Now, in the first paragraph of this study
10	was fabricated in part by a company known as FEG;	10	excuse me, in the abstract in this study, you note on
11	correct?	11	the right side
12	A. Please, can you can you please repeat it.	12	MR. THOMAS: Can you bring that up, please?
13	MR. THOMAS: Can you read that back, please.	13	It's 0697.
14	THE COURT REPORTER: "And the machine that	14	MR. KAUFFMANN: Which page?
15	you developed in 2007 was fabricated in part by a	15	MR. THOMAS: Front page. Excuse me. Let's
16	company known as FEG; correct?"	16	go to page the third page of that article.
17	THE WITNESS: I don't think they fabricated	17	Under Prolift+M system Gynemesh and Ultrapro,
18	any part of this machine.	18	first sentence.
19	BY MR. THOMAS:	19	BY MR. THOMAS:
20	Q. And what do you base that on?	20	Q. "Without any strain, the effective porosity
21	A. Because the FEG makes meshes and doesn't make	21	was 57.5 percent, and the majority of pores had a
22	any computer hardware, photograph, image maker, so	22	diameter of larger than 100 microns" "1,000
23	nothing no component of this machine can be done	23	microns."
24	by the FEG.	24	Correct?
_	Page 111		Page 113
1	Q. Okay.	1	A. Prolift+M, yeah. Yeah. You read it
2	A. So I think they Professor Mühl bought it	2	correctly.
3	from or has made it from their own engineers from	3	Q. Okay. And back on the first page in the
4	the university.	4	abstract on the right side, you identify the fact
5	 Q. Okay. Have you read the depositions of 	l _	
		5	that Prolift in tension-free can be considered a
6	Professor Mühl?	6	large pore Class I mesh; correct?
7	Professor Mühl? A. I guess I have, yeah.	6 7	large pore Class I mesh; correct? A. Yes. It's one of bigger it has one of the
7 8	Professor Mühl? A. I guess I have, yeah. Q. Okay. Did you recall any testimony he gave	6 7 8	large pore Class I mesh; correct? A. Yes. It's one of bigger it has one of the biggest pores of all mesh available.
7 8 9	Professor Mühl? A. I guess I have, yeah. Q. Okay. Did you recall any testimony he gave in that regard?	6 7 8 9	large pore Class I mesh; correct? A. Yes. It's one of bigger it has one of the biggest pores of all mesh available. Q. And down at the bottom you say that both
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7 8 9 10 11 12 13 14 15 16 17 18 19 20	Professor Mühl? A. I guess I have, yeah. Q. Okay. Did you recall any testimony he gave in that regard? A. No. Q. All right. When you did your testing back in 2005 to 2007 and you developed this machine, did you do it in conjunction with the FEG? A. Yes. It was a it was a funded project by the ministry together with the FEG and Professor Mühl, yeah. Q. And the FEG manufactures meshes? A. Yes. Q. And the FEG makes PVDF meshes; correct? A. Yes.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	large pore Class I mesh; correct? A. Yes. It's one of bigger it has one of the biggest pores of all mesh available. Q. And down at the bottom you say that both meshes this is on the right side of the first page. "Both meshes can be classified as large pore Class I mesh with an effective porosity that is sufficient to prevent bridging of scar tissue throughout the entire pore." Correct? A. I didn't didn't couldn't follow where you have been reading. Q. I'm down MR. ANDERSON: You changed. He was down in the abstract. You're moving down. BY MR. THOMAS:
7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	Professor Mühl? A. I guess I have, yeah. Q. Okay. Did you recall any testimony he gave in that regard? A. No. Q. All right. When you did your testing back in 2005 to 2007 and you developed this machine, did you do it in conjunction with the FEG? A. Yes. It was a it was a funded project by the ministry together with the FEG and Professor Mühl, yeah. Q. And the FEG manufactures meshes? A. Yes. Q. And the FEG makes PVDF meshes; correct? A. Yes. Q. And PVDF meshes are the meshes that you	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	large pore Class I mesh; correct? A. Yes. It's one of bigger it has one of the biggest pores of all mesh available. Q. And down at the bottom you say that both meshes this is on the right side of the first page. "Both meshes can be classified as large pore Class I mesh with an effective porosity that is sufficient to prevent bridging of scar tissue throughout the entire pore." Correct? A. I didn't didn't couldn't follow where you have been reading. Q. I'm down MR. ANDERSON: You changed. He was down in the abstract. You're moving down.

29 (Pages 110 to 113)

	Page 114		Page 116
1	to the Prolene Soft Mesh for hernia repair, and the	1	Q. Where is your basketball net?
2	textile structure of the Prolift+M system is copied	2	A. We don't have ball.
3	from the Ultrapro hernia mesh."	3	Q. Don't need a ball.
4	A. Is identical, yes.	4	A. Okay.
5	Q. "Both meshes can be classified as large pore	5	MR. ANDERSON: Would you like to use my net,
6	Class I mesh with an effective porosity that is	6	Dave?
7	sufficient to prevent bridging of scar tissue	7	MR. THOMAS: I would, please.
8	throughout the entire pore."	8	BY MR. THOMAS:
9	That's true?	9	Q. I don't remember what number we attached to
10	A. You read no, that's not true, but you read	10	this net, but I want to ask you some questions about
11	it correctly. It's not true if you applied some	11	the net.
12	forces to it.	12	You used the net to describe to the jury
13	Q. Okay. Well, this	13	forces that are present in the pelvic floor; correct?
14	A. This is just restricted to the situation	14	A. No. I want to demonstrate what happens to a
15	where you don't apply any forces.	15	pore if you applied some forces.
16	Q. Okay. And it's only if you apply forces to	16	Q. Okay.
17	it that, as far as you're concerned, it loses the	17	A. And you see the pore collapse. That is a
18	adequate pore size to prevent against this bridging;	18	fact.
19	correct?	19	Q. Now, when you tested the mesh like you did in
20	A. Then, yes, it's correct that this mesh then	20	Exhibit 0697, you attached one end of the mesh to one
21	change to a small pore, dangerous high risk device.	21	point and then pulled it in one direction; correct?
22	Q. All right. Now, the testing that you have in	22	A. Yes.
23	Exhibit 0697, you were retained as a plaintiff's	23	Q. And if you could show that to the jury. Hold
24	expert at this time; correct?	24	one end and pull.
	Dago 11E		
	Page 115		Page 117
1	A. I did not understand this.	1	Page 117 A. (Complying.)
1 2		1 2	
	A. I did not understand this.Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this		A. (Complying.)
2	A. I did not understand this.Q. You were a plaintiff's you were an expert	2	A. (Complying.)Q. And that's how that's how you tested it in
2	A. I did not understand this.Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this	2 3	A. (Complying.)Q. And that's how that's how you tested it in your study; correct?
2 3 4	 A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection 	2 3 4	 A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS:
2 3 4 5	 A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? 	2 3 4 5	 A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000
2 3 4 5 6	 A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. 	2 3 4 5 6	 A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS:
2 3 4 5 6 7	 A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study 	2 3 4 5 6 7	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct?
2 3 4 5 6 7 8 9	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation	2 3 4 5 6 7 8	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes.
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2 3 4 5 6 7 8 9 10 11 12	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct?	2 3 4 5 6 7 8 9 10 11	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it?
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct? A. Yes. Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct? A. Yes. Q. And it's also correct that you show in this article that the or purport to show that the DynaMesh retains a better effective porosity than the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it? A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are should be or should it should be possible to estimate them if you're thinking of uniaxial, from one direction.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct? A. Yes. Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct? A. Yes. Q. And it's also correct that you show in this article that the or purport to show that the DynaMesh retains a better effective porosity than the Ethicon mesh under strain; correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it? A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are should be or should it should be possible to estimate them if you're thinking of uniaxial, from one direction. Q. And when you place the mesh in the body
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct? A. Yes. Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct? A. Yes. Q. And it's also correct that you show in this article that the or purport to show that the DynaMesh retains a better effective porosity than the Ethicon mesh under strain; correct? A. We showed that there is an option to do it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it? A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are should be or should it should be possible to estimate them if you're thinking of uniaxial, from one direction. Q. And when you place the mesh in the body spread out the net
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct? A. Yes. Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct? A. Yes. Q. And it's also correct that you show in this article that the or purport to show that the DynaMesh retains a better effective porosity than the Ethicon mesh under strain; correct? A. We showed that there is an option to do it without collapse of the pores, and this is done by	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it? A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are should be or should it should be possible to estimate them if you're thinking of uniaxial, from one direction. Q. And when you place the mesh in the body spread out the net A. (Complying.)
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. I did not understand this. Q. You were a plaintiff's you were an expert for Mr. Anderson at the time you did the work on this paper; correct? A. Yes. Q. And you were paid for your time in connection with this work; correct? A. Yes. Q. And you didn't disclose that in the study that you were an expert for plaintiffs in litigation against Ethicon at the time that you did this study; correct? A. Yes. Q. And it's also correct that you didn't disclose in this study that you were a consultant for the FEG; correct? A. Yes. Q. And it's also correct that you show in this article that the or purport to show that the DynaMesh retains a better effective porosity than the Ethicon mesh under strain; correct? A. We showed that there is an option to do it	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. (Complying.) Q. And that's how that's how you tested it in your study; correct? A. Yeah. Similar to the way Ethicon did it. MR. THOMAS: Move to strike after "yes." BY MR. THOMAS: Q. And you applied weights of 100 grams to 1,000 grams to the other end of the mesh in order to get your results; correct? A. If you're talking of this study, yes. Q. Now, in the body, mesh undergoes forces from multiple directions, doesn't it? A. It depends whether it functions as a replacement of ligaments or whether it is a function as a flat area, but, of course, you always have forces from all sides wherever you are in the world. But if you are thinking of ligaments, the relevant forces are should be or should it should be possible to estimate them if you're thinking of uniaxial, from one direction. Q. And when you place the mesh in the body spread out the net

	Page 118		Page 120
1	A. Yes.	1	A. Yes.
2	Q. And it's applied tension-free so that the	2	Q. And it's not only the one directional force
3	tissue in the pores is what actually holds the mesh	3	that you used in your test model; correct?
4	into place; correct?	4	A. The one direction force is the best
5	MR. ANDERSON: Objection.	5	approximation for the ligaments, for the arms.
6	Go ahead.	6	Q. But my
7	THE WITNESS: Yes.	7	A. Not for the others. I agree. Not for the
8	BY MR. THOMAS:	8	flat mesh area. Then it is not the best way.
9	Q. And you've not done any testing of mesh with	9	Q. And it's possible to design a test that
10	tissue in it, have you? Excuse me. Strike that.	10	allows for mesh being pulled in multiple directions
11	You have not done any effective porosity	11	and also to account for weight on the top of the
12	testing of mesh with tissue in it, have you?	12	mesh?
13	A. We didn't do it is impossible to do it	13	A. As I said, no. Not sufficiently. You can
14	with this machine, to have a testing of the effective	14	design such a test where you put forces from various
15	porosity, a measurement of the effective porosity	15	directions, but the interpretation of these results
16	with tissue inside.	16	is very difficult; and overall as a setup to reflect
17	Q. Okay. And you know that it's possible to	17	the situation in the body, it is insufficient.
18	design a test that tests the forces on the mesh from	18	Q. As a matter of fact, the test that you did in
19	multiple directions, don't you?	19	both 2007 and 2013 is insufficient to determine the
20	A. I know that there are experimental settings	20	extent to which this test can be applied to the
21	doing this, but it is a it is impossible to model	21	development of better meshes; correct?
22	the situation in a pelvis in with any of these	22	A. No.
23	settings completely. It's every time	23	Q. Let me show you go back to your study,
24	everything is just an arbitrary trial that you can	24	Plaintiff's 0697.
	Page 119		Page 121
1	try to model it, but it's not never perfect.	1	In 2013, the last sentence of the abstract,
2	Q. But you agree it's possible to construct a	2	it says, "The clinical studies have to prove whether
3	test that measured forces applied in different	3	devices with high porosity as well as high structural
4	directions of the mesh; correct?	4	stability can improve the patient's outcome."
5	A. You can make a setting where you apply some	5	Did I read that correctly?
6	forces from two directions, but it never reflects a	6	A. Yes.
7	situation of a mesh that is incorporated into tissue.	7	Q. And in 2007
8	Never.	8	MR. THOMAS: Can I have a sticker, please.
9	Q. So when	9	I'm going to mark this as Klinge Trial
10	A. There's no way.	10	Deposition Exhibit Number 1.
11	Q. When you you can design a strike that.	11	
12	When mesh is implanted in the human body, the	12	(Klinge Trial Deposition Exhibit No. 1,
13	stresses that are applied to that mesh are both	13	Article entitled "New Objective Measurement to
14	lengthwise, top to bottom, diagonally; correct?	14	Characterize the Porosity of Textile Implants," Bates
15	A. It depends from the location and of the	15	stamped DX31026.1 through DX31026.8, was marked for
16	function and of the size of the mesh whether the	16	identification.)
17	model has to include these differences or whether	17	
	it's possible to just think of one direction, and all	18	BY MR. THOMAS:
18		l	Q. Let me show you what I have marked as Klinge
18 19	mechanical testing setups are insufficient or	19	£. =
	mechanical testing setups are insufficient or computer simulations until now are insufficient to	19 20	Trial Deposition Exhibit Number 1.
19			•
19 20	computer simulations until now are insufficient to	20	Trial Deposition Exhibit Number 1.
19 20 21	computer simulations until now are insufficient to model this.	20 21	Trial Deposition Exhibit Number 1. MR. ANDERSON: Thank you.

	Page 122		Page 124
1	A. Yes.	1	A. The problem that they are not there are
2	Q. And in this study, you and Professor Mühl did	2	because the old meshes, the small pore meshes, as
3	uniaxial testing on DynaMesh and other meshes	3	Prolift, they all belong to the category of these
4	manufactured in Europe; correct?	4	small pore thing.
5	A. Yes.	5	Q. Okay.
6	Q. And you found in 2007 that the DynaMesh	6	A. How we don't have sufficient explants from
7	retained its effective porosity and the other meshes	7	large pore materials with a high structural stability
8	did not; correct?	8	in the moment, but we are still collecting these
9	A. No.	9	materials.
10	Q. Not true?	10	Q. Can you answer my question yes or no? Let me
11	A. No, that's not true.	11	ask it again.
12	Q. Did DynaMesh retain its effective porosity?	12	In 2013, Doctor, you state in this study,
13	A. Yes, but Sofradim light as well.	13	"Clinical studies have to prove whether devices with
14	Q. Okay. And at the end of the study in 2007,	14	high porosity, as well as high structural stability,
15	you say that, in the abstract, "Further in vivo	15	can improve the patients' outcome."
16	studies have to investigate whether the preservation	16	There's still no clinical studies that prove
17	of a high effective porosity under stress may help to	17	whether devices with high porosity as well as high
18	improve biocompatibility of textile implants."	18	structural stability can improve the patients'
19	Is that correct?	19	outcome; true?
20	A. Yes.	20	A. There are no comparative clinical studies at
21	Q. And "in vivo studies" means studies in	21	all.
22	animals?	22	Q. Thank you.
23	A. Amongst all, but more or less the most	23	Now, Doctor, in this study in both 2007 and
24	important way to learn what happens to the meshes is	24	in 2013, you identified 1,000 microns or 1 millimeter
	Page 123		Page 125
1		1	
1 2	the analyses of explanted materials from humans.	1 2	as the standard of effective porosity in
2	the analyses of explanted materials from humans. Q. Okay. The study says further in vivo	2	as the standard of effective porosity in polypropylene; correct?
2	the analyses of explanted materials from humans.		as the standard of effective porosity in polypropylene; correct? A. Yes, that is what we used.
2	the analyses of explanted materials from humans. Q. Okay. The study says further in vivo studies. That means studies of mesh in animals; correct? Isn't that what that means?	2 3	as the standard of effective porosity in polypropylene; correct?
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2 3 4 5	the analyses of explanted materials from humans. Q. Okay. The study says further in vivo studies. That means studies of mesh in animals; correct? Isn't that what that means?	2 3 4 5	as the standard of effective porosity in polypropylene; correct? A. Yes, that is what we used. Q. But you used 600 microns for PVDF; correct? A. Yes. Q. Now, it's true in the context of effective
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2 3 4 5 6 7 8	the analyses of explanted materials from humans. Q. Okay. The study says further in vivo studies. That means studies of mesh in animals; correct? Isn't that what that means? A. I guess at that time we thought that this was a setting in a lab without any tissue, without any biology, and we said this testing from the lab has to be transferred to the biology, and this	2 3 4 5 6 7 8	as the standard of effective porosity in polypropylene; correct? A. Yes, that is what we used. Q. But you used 600 microns for PVDF; correct? A. Yes. Q. Now, it's true in the context of effective porosity, if a pore is reduced by even 10 microns, to 990 microns, it does not get counted in a porosity
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	the analyses of explanted materials from humans. Q. Okay. The study says further in vivo studies. That means studies of mesh in animals; correct? Isn't that what that means? A. I guess at that time we thought that this was a setting in a lab without any tissue, without any biology, and we said this testing from the lab has to be transferred to the biology, and this therefore, we said we need this in vivo studies, and there's no specification to animal or reduction to animals. Q. There have been no in vivo studies to investigate whether the preservation of a high effective porosity under stress may help to improve biocompatibility of textile implants, has there? A. Not before, because this was the presentation of this this conception. Q. And in 2013 in Exhibit 0697, you repeat, the clinical studies have to prove whether devices with high porosity as well as high structural stability could improve the patient's outcome. There's still no clinical studies that prove wherefore devices with	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	as the standard of effective porosity in polypropylene; correct? A. Yes, that is what we used. Q. But you used 600 microns for PVDF; correct? A. Yes. Q. Now, it's true in the context of effective porosity, if a pore is reduced by even 10 microns, to 990 microns, it does not get counted in a porosity calculation; correct? A. That is correct. Q. And so it's only pores with 1,000 microns in all directions that are included in the effective porosity calculation; correct? A. That depends on the polymer. If you have another polymer where you know that it behaves a little bit better, then it is very easy to change the machine. It is objective, reproducible, reliable. So if you, as a manufacturer, have a polymer where you know that it is critical diameter would be only 900 microns, yeah, then you can make these measurements with your critical diameter. Q. Okay. And the machine

	Page 126		Page 128
1	but yeah.	1	A. He used another classification.
2	Q. But you didn't those are the only two	2	Q. Okay. That's my point. He describes the
3	measurements you took, at 1,000 for polypropylene and	3	synthetic implant materials for Prolene and Marlex as
4	600 for PVDF; correct?	4	totally microporous; correct?
5	A. Measurements, there have been a lot, but	5	A. That is correct.
6	these are the two, yeah. If you applied this	6	Q. And he disagrees with your classification?
7	measurement to this machine for polypropylene, you	7	A. No. No. There is no not any data showing
8	can put in only one range.	8	that the bridging doesn't occur. There is not any
9	Q. Okay.	9	data that 1 millimeter is not a critical limit. The
10	A. One limit.	10	only thing that happens is he used the classification
11	Q. You know, other scientists disagree with your	11	of Amid, who was produced when we start before we
12	1,000 figure for polypropylene, don't they?	12	started our joint collaboration with Ethicon, and at
13	A. I'm not aware of anyone who said that the	13	that time there hasn't been any large pore mesh. So
14	pore size and the bridging does not happen, no.	14	Amid was not able to consider these large pore meshes
15	Q. Okay.	15	in his classification. So when using this old
	· · · · · · · · · · · · · · · · · · ·		classification, of course, you will have a mix of
16	A. And I don't know any measurements showing	16	· · · · · · · · · · · · · · · · · · ·
17	that it is different.	17	these terms.
18	MR. ANDERSON: Keep this separate.	18	Q. Okay.
19		19	A. But it doesn't is relevant in any way to
20	(Klinge Trial Exhibit No. 2, Article entitled	20	the fact that small pores have an increased risk,
21	"Synthetic and biodegradable prostheses in pelvic	21	makes it unsafe and are filled by scar tissue.
22	floor surgery," Bates stamped DX3036.1 through	22	Q. Go to the bottom.
23	DX3036.11, was marked for identification.)	23	A. So no.
24		24	Q. I'm sorry. Go to the bottom of page 4.
	Page 127		Page 129
1	BY MR. THOMAS:	1	A. Yeah.
2	Q. Let me show you what's been marked as Klinge	2	Q. And Dr. Deprest says that, "Pore sizes
3	Trial Exhibit Number 2. It's an article by Deprest	3	greater than 75 microns allow for rapid ingrowth of
4	and others.	4	fibroblasts and vascular elements necessary to anchor
5	A. Yes.	5	the implant within the native tissue."
6	Q. Are you familiar with this article?	_	_
		6	That's what he says, isn't it?
7	A. I think a long time ago I read it.	7	That's what he says, isn't it? A. Yes.
_	A. I think a long time ago I read it.O. And this is an article in 2005?	7	A. Yes.
7 8 9	Q. And this is an article in 2005?	7 8	A. Yes. Q. Okay. Is that correct?
8 9	Q. And this is an article in 2005?A. Yes.	7 8 9	A. Yes.Q. Okay. Is that correct?A. The fact is
8 9 10	Q. And this is an article in 2005?A. Yes.Q. About the same time that you came out with	7 8 9 10	A. Yes.Q. Okay. Is that correct?A. The fact isQ. Is it correct?
8 9 10 11	Q. And this is an article in 2005?A. Yes.Q. About the same time that you came out with your article about 1,000 millimeters; correct?	7 8 9 10 11	A. Yes.Q. Okay. Is that correct?A. The fact isQ. Is it correct?MR. ANDERSON: Is what correct?
8 9 10 11 12	Q. And this is an article in 2005?A. Yes.Q. About the same time that you came out with your article about 1,000 millimeters; correct?A. Obviously.	7 8 9 10 11 12	 A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS:
8 9 10 11 12 13	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? 	7 8 9 10 11 12 13	 A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with
8 9 10 11 12 13 14	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. 	7 8 9 10 11 12 13 14	 A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that?
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8 9 10 11 12 13 14 15 16 17 18	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct? A. Obviously, yeah. Q. If you turn to page 4 of Klinge Trial 	7 8 9 10 11 12 13 14 15 16 17 18 19	A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that? A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of
8 9 10 11 12 13 14 15 16 17 18 19 20	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct? A. Obviously, yeah. Q. If you turn to page 4 of Klinge Trial Deposition Exhibit 2, there's a description of Type I 	7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that? A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of the holes. If you are agreed that you want to have
8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct? A. Obviously, yeah. Q. If you turn to page 4 of Klinge Trial Deposition Exhibit 2, there's a description of Type I meshes. Do you see that? 	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that? A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of the holes. If you are agreed that you want to have scar in your implant, then, of course, yeah, this is
8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct? A. Obviously, yeah. Q. If you turn to page 4 of Klinge Trial Deposition Exhibit 2, there's a description of Type I meshes. Do you see that? A. Yes. 	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that? A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of the holes. If you are agreed that you want to have scar in your implant, then, of course, yeah, this is correct.
8 9 10 11 12 13 14 15 16 17 18 19 20 21	 Q. And this is an article in 2005? A. Yes. Q. About the same time that you came out with your article about 1,000 millimeters; correct? A. Obviously. Q. And do you know Dr. Deprest? A. Yes, very well. Q. And he's writing about synthetic and biodegradable prostheses in pelvic floor surgery; correct? A. Obviously, yeah. Q. If you turn to page 4 of Klinge Trial Deposition Exhibit 2, there's a description of Type I meshes. Do you see that? 	7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. Q. Okay. Is that correct? A. The fact is Q. Is it correct? MR. ANDERSON: Is what correct? BY MR. THOMAS: Q. Is that statement correct? Do you agree with that? A. The statement is only correct if you assume that you need a pore size of 75 microns to allow scar to get integrated. Our point is that we want to separate the integration of fat and scar, and, therefore, you need a completely different size of the holes. If you are agreed that you want to have scar in your implant, then, of course, yeah, this is

33 (Pages 126 to 129)

	Page 130		Page 132
1	there is no fact to it. It is a citation of Amid's	1	A. The next sentence.
2	classification and nothing more.	2	Q. Yes. Larger
3	Q. Okay. You could have changed the settings on	3	A. "Larger pores limit the fibrosis process to
4	your effective porosity testing to measure for 75	4	perifilament region and the pores get filled with
5	microns; correct?	5	fat."
6	A. Everyone can do it. Yeah.	6	Q. Right. But you didn't do any testing on your
7	Q. But you didn't do that?	7	effective porosity machine at 400 to 500 microns, did
8	A. No.	8	you?
9	Q. Let me show you now what's been marked as	9	A. We didn't make a calculation exactly with
10	and, by the way, he was joined in that study by eight	10	this one, no.
11	other people on the study; correct? On the first	11	Q. Okay. And do you agree with Dr. Deprest that
12	page you can count the people who were involved in	12	in the use of implants in pelvic organ prolapse
13	the study.	13	repair that peak ingrowth is reached at pore size
14	A. Yeah.	14	around 4- to 500 microns? Do you agree with that?
15		15	A. If you are this is while you are coming
16	(Klinge Trial Deposition Exhibit No. 3,	16	from tissue engineering, and it is not the value that
17	Article entitled "The biology behind fascial defects	17	helps us to define whether you have fat and scar
18	and the use of implants in pelvic organ prolapse	18	tissue. Therefore, it is no argument against the
19	repair," Bates stamped DX30360.1 through DX30360.10,	19	relevance of effective porosity for the clinical
20	was marked for identification.)	20	outcome.
21		21	Q. Okay. But you didn't measure at 4- or 500
22	BY MR. THOMAS:	22	microns, which is the peak level identified by
23	Q. Let me show you now what I have had marked as	23	Dr. Deprest, did you?
24	Klinge Trial Exhibit Number 3. And this is a	24	A. In what in what sense should
	Page 131		Page 133
1	another paper a year later by Dr. Deprest; correct?	1	Q. Yeah. You didn't conduct those tests on
2	A. Yes.	2	A. If
3	Q. It's in 2006. This is a year after your	3	Q either DynaMesh or on polypropylene in the
4	paper; correct?	4	tests you did with Professor Mühl; correct?
5	A. Yes.	5	A. If we place a mesh into this machine and
6	Q. And if you'll go to page 3 of this trial	6	defined the critical size of, let's say, 200 microns,
7	Exhibit 3, once again, he cites to the Amid	7	yeah, there will never be an effective pore pore
8	classification; correct? Down on the right, lower	8	that will be filled by fat tissue.
9	right-hand corner?	9	Q. My
10	A. Yes.	10	A. We know this, yeah.
11	Q. And you see the classification of implants	11	Q. My point is, Doctor, you didn't test at the
12	where it talks about macroporous that's with an	12	areas identified by Dr. Deprest as being the peak
13	a that's greater than 75 microns. Do you see	13	ingrowth for tissue as cited in the exhibit I just
14	that?	14	gave you. You've not done that, have you? True?
15	A. Yeah.	15	A. But in the
16	Q. And it says in the lower right-hand side	16	Q. Is it true?
17	that, "Pore sizes greater than 75 microns allow for	17	A. We never modified this testing with these
18	rapid ingrowth of fiberglass and vascular elements	18	data, yes, that is true.
I	necessary to anchor the implant within the native	19	Q. Okay.
19			A. But it doesn't make any sense.
20	tissue. Peak ingrowth is reached at pore size around	20	The Back to decising manifesting sense.
20 21	400 to 500 microns."	21	
20 21 22	400 to 500 microns." Did I read that correctly?	21 22	(Defendant's Exhibit No. DX30064, Article
20 21	400 to 500 microns."	21	

	Page 134		Page 136
1	surgery," Bates stamped DX30064.1 through DX30064.7,	1	Q. It's fair to understand, Doctor, that the two
2	was marked for identification.)	2	studies that you did with Professor Mühl that we've
3		3	had marked one as Plaintiff's 0697 and the other as
4	BY MR. THOMAS:	4	Klinge Trial Exhibit Number 1, are not, standing
5	Q. All right. And you know that there are some	5	alone, able to replicate what happens in the human
6	people let me show you what's been marked as	6	body; correct?
7	Defendant's Exhibit 30064, and 30064 is the Amid	7	A. They are able to replicate some aspects.
8	paper from 1997. You recognize that?	8	Q. Okay. But the whole point of these studies
9	MR. ANDERSON: I'm sorry, Counsel. Is this	9	is to give people a starting point so that you can
10	going to be a defense exhibit? Because the other	10	use this information to develop a better model to
11	ones you used a defense exhibit for Klinge. Do	11	understand what happens in the human body; correct?
12	you want it to be a Klinge exhibit? Because	12	A. It helps to predict the risk for rigid
13	you	13	fibrosis without any forces and what happens to your
14	MR. THOMAS: I know that. And just for your	14	textile, to your device when you applied some forces.
15	benefit and my admission, I didn't realize when I	15	Therefore, it gives a measure so that you can
16	marked them that they had numbers on them. All	16	optimize the design of the meshes, yeah.
17	I'm trying to do is not create new numbers if I	17	Q. Uniaxial forces only; correct?
18	can.	18	A. Uniaxial forces, yeah. And you can modify
19	MR. ANDERSON: Okay.	19	the forces. You can modify the diameter depending on
20	MR. THOMAS: And we'll change we'll change	20	the polymer you are using. So a very standardized
21	the numbers at a later time if I have to.	21	technique, open for everyone.
22	MR. ANDERSON: So that it correlates with	22	Q. And so when you go back to Plaintiff's 0697
23	your exhibit numbers. Okay. That's fine.	23	and you go to page 5
24	MR. THOMAS: I'm just trying to identify them	24	MR. ANDERSON: Hold on. Let's get 06
1		1	that's not it.
1 2	as best I can. MR. ANDERSON: Yeah.	2	MR. THOMAS: It's the 2013 study.
3	BY MR. THOMAS:	3	MR. ANDERSON: Yeah. But I moved stuff.
3 4		4	Here.
5	Q. Now, Doctor, I've shown you Defendant's	5	THE WITNESS: Five.
6	Exhibit 30064, and this is the Amid paper that we	6	BY MR. THOMAS:
7	have been talking about, isn't it? A. Yes.	7	Q. Are you there? The porosity of the
_	Q. And this is what has been known as the Amid		Gynemesh PS and the Gynemesh and the DynaMesh, I'm
8 9	classifications since 1997; correct?	8 9	sorry, are measured, on the very top of that article.
10	A. Yes.	10	Do you see that?
11	Q. And you know that there's some people that	11	A. Where are you?
12	still follow the Amid classification; correct?	12	Q. Is that textile porosity where it says
13	A. I personally will follow it when when	13	porosity at percentage?
14	looking at the risk for infection and material	14	A. I guess it's the textile porosity.
15	infection, I it's still proper to follow this	15	Q. Okay. Do you know what it is?
16	classification. If you want to separate the bridging	16	A. The textile porosity is the area that is not
17	fibrosis, the scarring of the pores, it is not	17	covered by the ligaments.
18	appropriate.	18	Q. Okay.
19	Q. But that's you. You know that there are some	19	A. So maybe this is the easiest definition of
20	scientists who still follow the Amid class at this	20	this one.
21	indication?	21	Q. Do you know under Gynemesh where it's 62.9,
21	A. Depends on the purpose why.	21	do you know what that represents?
22	11. Depends on the purpose WHV.	. 44	do you know what that represents:
22 23			A Where you are?
22 23 24	Q. Okay. Thank you. A. What do you want to have with the yeah.	23 24	A. Where you are?Q. Under porosity at the top in the figure, in

	Page 138		Page 140
1	Figure 3 on the far left. Doctor Doctor, if you	1	Q. Okay.
2	look at page 5	2	A. There's no way.
3	A. Yeah.	3	Q. So the answer is there are no studies?
4	Q of Exhibit 0697, I'm looking at	4	A. There are no studies proving the safety or
5	Gynemesh PS with no force, zero newtons per	5	the superiority of any of these devices.
6	centimeter, under arm 1, and there's a figure 62.9.	6	Q. Now, Doctor, when we talked about in vivo
7	A. Yeah.	7	studies, we're talking about studies conducted in
8	Q. What does that mean?	8	animals; correct?
9	A. That means when you made an image, that 67	9	A. It's one part, yeah.
10	62.9 percent of this area is not covered by	10	Q. And you used rats in studies to help
11	filaments.	11	determine types of inflammatory reactions which occur
12	Q. Okay. And that's arm 1; correct?	12	with implanted meshes, haven't you?
13	A. That's arm 1.	13	A. In this collaboration that we started
14	Q. And then arm 3 is 60.1; correct?	14	together with Ethicon, we used rats, rabbits and
15	A. Yeah.	15	other animals. So depending on the specific
16	Q. And if you compare that with DynaMesh arm 1,	16	question, we need different models.
17	that is equal to or greater than the value for	17	Q. And the reason why you did that was so that
18	DynaMesh; correct?	18	you could place mesh in animals and study the tissue
19	A. Yes.	19	response to that mesh; correct?
20	Q. Okay. Now, you agree that biocompatibility	20	A. Yes.
21	of long-term implantable devices can be defined as	21	Q. And you also used rats in studies to
22	the ability of the device to perform its intended	22	determine the extent to which mesh integrates into
23	function with the desired degree of incorporation in	23	the tissues of the rat?
24	the host without eliciting any undesirable, local or	24	A. As I told you, we use rats, rabbits, but we
	,		
	Page 139		Page 141
1	systematic effects in the host?	1	confirmed all these results by looking at the human
2	A. Yes.	2	explants.
3	Q. And you know of no studies strike that.	3	Q. And the reason why you wanted to strike
4	You agree that Prolene Soft Mesh has a better	4	that.
5	biocompatibility than the Prolene mesh used in hernia	5	You used rats in studies to determine the
6	repair?	6	extent to which the mesh implanted into the rat
7	A. It depends on the specific design and of	7	integrates into the tissues; correct?
8	the different it depends from the location and	8	A. I didn't get the entire question.
9	Q. Do you have an opinion	9	Q. Let me ask it again.
10	A to place it.	10	In your experience, you use rats in studies
11	Q. Do you have an opinion about whether Prolene	11	to determine the extent to which the mesh implanted
12	Soft Mesh has a better biocompatibility than Prolene?	12	in the rats integrates into the tissues of the rats;
13	A. I cannot answer it. I have an opinion, but	13	correct?
14	it cannot be answered just by yes or no.	14	A. Yes.
15	Q. Okay.	15	Q. Okay. And you know that Ethicon has
16	MR. ANDERSON: I have the same objection.	16	conducted tissue reaction and tissue integration
17	Outside the scope of direct.	17	studies where Ethicon implanted mesh in animals,
18	BY MR. THOMAS:	18	don't you?
19	Q. And you know of no studies in a randomized	19	A. Yes, I know.
20	controlled trial which compare the biocompatibility	20	Q. And you have reviewed some of those studies;
21	of Prolene Soft Mesh with another mesh; correct?	21	correct?
22	A. There is no way to make a clinical trial	22	A. Yes.
	where this question with sufficient statistical	23	
23	where this question with sufficient statistical		
23 24	power.	24	(Klinge Trial Exhibit No. 4, Ethicon Final

	Page 142		Page 144
1	Report, PSE Accession No. 00-0035, An Exploratory	1	into the mesh; correct?
2	91-day Tissue Reaction Study of Polypropylene-based	2	A. You have to define it very carefully what
3	Surgical Mesh in Rates (PSE ACC. NO. 00-0035), was	3	what type of tissue, what are which cells you are
4	marked for identification.)	4	looking at, what happens in the pores, which is your
5		5	area of interest. So research is not so simple just
6	BY MR. THOMAS:	6	to say we are making it and looking to this, no.
7	Q. I'm going to show you what I have marked as	7	Q. Okay.
8	Klinge Trial Exhibit Number 4.	8	A. It is
9	Dr. Klinge, Klinge Trial Exhibit Number 4 is	9	Q. You understood that this study placed mesh
10	a document titled document dated July 11, 2001.	10	under the skin of rats
11	It's a final report, and it's titled, "An Exploratory	11	A. Yeah.
12	91-Day Tissue Reaction Study of Polypropylene-Based	12	Q in order to look at the tissue reaction to
13	Surgical Mesh in Rats."	13	that mesh as well as to analyze the extent to which
14	You've seen that before, haven't you?	14	the tissue integrated into the mesh. You understand
15	A. I think I saw it, yeah.	15	that was a goal of this study?
16	Q. And you reviewed that in connection with your	16	A. Yeah. We did it several time ourselves
17	work in this litigation, didn't you?	17	but
18	A. Yes.	18	Q. Same type
19	Q. And you did not see this study before this	19	A we know the limitations of this very, very
20	litigation; correct?	20	well.
21	A. That is correct.	21	Q. I understand. But you've done this same type
22	Q. And Ethicon conducted this study in the	22	of study yourself with different animals and
23	period 2000 to 2001; correct?	23	different meshes?
24	A. It should be correct.	24	A. And for some other purposes with this
	Page 143		Page 145
1	Q. And let's go to page 2 of 27 of this study.	1	specific hypothesis, yeah.
2	A. Two of 27.	2	Q. Okay. And if you turn the page, please, it
3	Q. See under "Summary"? Right there under	3	talks about materials. Do you see that?
4	"Summary."	4	A. There we are.
5	The first line, "A subcutaneous implantation	5	Q. We're on page 3 of 27
6	study was conducted to assess the tissue reaction	6	A. Yeah.
7	profile and qualitative integration of several	7	Q of Klinge Trial Exhibit Number 4.
8	different constructions of polypropylene surgical	8	A. Uh-huh. Bard, Surgipro, Prolene and Prolene
9	meshes."	9	Soft, Vypro.
10	Tell the jury what a subcutaneous	10	Q. And there are listed there seven different
1	3 3	1 10	Q. And there are listed there seven different
11	implantation study is.	11	meshes that are tested; correct?
11	implantation study is.	11	meshes that are tested; correct?
11 12	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on	11 12	meshes that are tested; correct? A. Yes.
11 12 13	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be	11 12 13	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a
11 12 13 14	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able,	11 12 13 14	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made
11 12 13 14 15	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the	11 12 13 14 15	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon?
11 12 13 14 15	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able,	11 12 13 14 15 16	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no.
11 12 13 14 15 16	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the	11 12 13 14 15 16 17	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no. Q. Excuse me. Bard mesh is not made by Ethicon;
11 12 13 14 15 16 17	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the material and look to the tissue reaction to this.	11 12 13 14 15 16 17	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no. Q. Excuse me. Bard mesh is not made by Ethicon; correct?
11 12 13 14 15 16 17 18	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the material and look to the tissue reaction to this. Q. Okay. And you can look to both the tissue	11 12 13 14 15 16 17 18 19	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no. Q. Excuse me. Bard mesh is not made by Ethicon; correct? A. That is correct.
11 12 13 14 15 16 17 18 19	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the material and look to the tissue reaction to this. Q. Okay. And you can look to both the tissue reaction, which is the how the body reacts to the	11 12 13 14 15 16 17 18 19 20	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no. Q. Excuse me. Bard mesh is not made by Ethicon; correct? A. That is correct. Q. Thank you.
11 12 13 14 15 16 17 18 19 20 21	implantation study is. A. A subcutaneous implantation study, then you usually place small pieces of a mesh in the subcutaneous area beneath underneath the skin on top of the muscles, so it's laying in fat. It can be done very easily. And, yeah, and then you are able, then, after some time that you can explant the material and look to the tissue reaction to this. Q. Okay. And you can look to both the tissue reaction, which is the how the body reacts to the mesh; correct?	11 12 13 14 15 16 17 18 19 20 21	meshes that are tested; correct? A. Yes. Q. And the Bard mesh that's tested there is a competitor's mesh, isn't it? Bard mesh is not made by Ethicon? A. No, no, no. Q. Excuse me. Bard mesh is not made by Ethicon; correct? A. That is correct. Q. Thank you. And that's what you referred to as a small

	Page 146		Page 148
1	manufactured by a competitor; correct?	1	Soft Mesh; correct?
2	A. Yes.	2	A. Yes.
3	Q. Now, Prolene mesh is a is the hernia mesh	3	Q. And the company tested Vypro mesh. You see
4	used by Ethicon that has a pore size smaller than the	4	that?
5	Prolift mesh; correct?	5	A. Yes.
6	A. How what is your definition of the pore	6	Q. And it tested three different kinds of Vypro
7	size and how it is measured? What is the pore size	7	mesh. Do you see that?
8	of the Prolift mesh? So it is insufficient. We know	8	A. Yes.
9	it meanwhile to give just one figure.	9	Q. And Vypro mesh is the mesh that you helped
10	Q. Without tension it is clear that the pore	10	Ethicon develop; correct?
11	size of the Prolene mesh used in hernia repair is	11	A. Yes.
12	smaller than the	12	Q. And Vypro mesh is the mesh that you
13	A. The area of affected pores maybe.	13	characterize as being lightweight large pore;
14	Q. Let me ask the question again, and let me	14	correct?
15	finish it before you give an answer.	15	A. Yes.
16	A. Sorry.	16	Q. And the company in Klinge Trial Exhibit
17	Q. Doctor, it's true that the area of the pore	17	Number 4 compared the tissue reaction and tissue
18	for the Prolene mesh used in hernia repair is smaller	18	integration of all seven of these meshes; correct?
19	than the pore size without tension of the pore size	19	A. Yeah.
20	of the Prolene polypropylene mesh used in Prolift?	20	Q. And they implanted these meshes in rats for
21	MR. ANDERSON: Objection.	21	7 days, 28 days, 63 days, and 91 days; correct?
22	THE WITNESS: Again, it would be necessary to	22	A. Yeah, that is correct.
23	make a testing of the effective porosity for the	23	Q. And after each of these time frames, some of
24	Prolene mesh. I didn't do it, so I know I	24	the rats were killed, sacrificed, and then the mesh
	Page 147		Page 149
1	Page 147 don't know it.	1	Page 149 removed so it could be analyzed; correct?
1 2		1 2	_
	don't know it.		removed so it could be analyzed; correct?
2	don't know it. BY MR. THOMAS:	2	removed so it could be analyzed; correct? A. Yeah.
2	don't know it. BY MR. THOMAS: Q. I'm not talking about effective porosity.	2	removed so it could be analyzed; correct? A. Yeah. Q. And when you removed the mesh from the animal
2 3 4	don't know it. BY MR. THOMAS: Q. I'm not talking about effective porosity. I'm not I'm talking about porosity at rest without tension. A. The textile porosity	2 3 4	removed so it could be analyzed; correct? A. Yeah. Q. And when you removed the mesh from the animal to be analyzed, how do you prepare samples? What's
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	Page 150		Page 152
1	Q. But a pathologist is what? What's a	1	put under a microscope; correct?
2	person what's a pathologist do?	2	A. Yeah.
3	A. A pathologist is someone who has the training	3	Q. And it's the microscopic observation by the
4	to investigate tissues that are extracted by some	4	person looking at it that causes him to reach the
5	surgical means or from some tissues, and there he was	5	conclusions that they express in the report; correct?
6	trained to identify the changes in these tissues.	6	A. No, not always. You have to look to the
7	Q. Now, you didn't work at the institute of	7	microscopical appearance of the explants as well. So
8	pathology at your hospital, did you?	8	the microscopical mainly is an explanation of what
9	A. No.	9	happens, but for the patient it's more important what
10	Q. And you don't you didn't do a residence in	10	happens clinically.
11	pathology, did you?	11	Q. You've never looked at the slides that this
12	A. No.	12	study generated in Klinge Trial Exhibit Number 4,
13	Q. And you had no fellowship in pathology, did	13	have you?
14	you?	14	A. I never got the slides from this study from
15	A. No.	15	study from Barbolt. I've seen it.
16	Q. As a matter of fact, you're not permitted to	16	Q. And you know they're still available, don't
17	sign pathology reports at your hospital; correct?	17	you?
18	A. That is correct.	18	A. What?
19	Q. Now	19	Q. You know they're still available, don't you?
20	A. But in research, the examination never is	20	A. They are still available?
21	done by the pathologist but by the researcher	21	Q. Yes. You haven't looked at it?
22	themselves.	22	A. I didn't get it, yes.
23	MR. THOMAS: Object. Move to strike	23	THE WITNESS: Is it possible to get?
24	everything after "that's correct."	24	BY MR. THOMAS:
	Page 151		Page 153
1	BY MR. THOMAS:	1	Q. Let's go to Plaintiff's Exhibit 271. That's
2	Q. Let's go to page 2. And page 2, the third	1	
_		2	your 2005 paper.
3	line down under "Summary," the summary finds, "The	3	your 2005 paper. MR. ANDERSON: That's not it.
4			
	line down under "Summary," the summary finds, "The	3	MR. ANDERSON: That's not it.
4	line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from minimal to mild in intensity and, thus, were all	3 4	MR. ANDERSON: That's not it. BY MR. THOMAS:
4 5	line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from	3 4 5	MR. ANDERSON: That's not it. BY MR. THOMAS: Q. And this is a paper that you prepared with
4 5 6	line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from minimal to mild in intensity and, thus, were all	3 4 5 6	MR. ANDERSON: That's not it. BY MR. THOMAS: Q. And this is a paper that you prepared with Dr. Klosterhalfen and Dr. Junge?
4 5 6 7	line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from minimal to mild in intensity and, thus, were all considered to be biocompatible." Did I read that correctly? A. Yes.	3 4 5 6 7	MR. ANDERSON: That's not it. BY MR. THOMAS: Q. And this is a paper that you prepared with Dr. Klosterhalfen and Dr. Junge? A. That is correct.
4 5 6 7 8	line down under "Summary," the summary finds, "The inflammatory reaction among the different constructions was relatively similar, ranging from minimal to mild in intensity and, thus, were all considered to be biocompatible." Did I read that correctly? A. Yes. Q. If you go to page 9, first line of the second	3 4 5 6 7 8	MR. ANDERSON: That's not it. BY MR. THOMAS: Q. And this is a paper that you prepared with Dr. Klosterhalfen and Dr. Junge? A. That is correct. Q. And would you call this a review article?
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39 (Pages 150 to 153)

	Page 154		Page 156
1	MR. THOMAS: That's my fault. I apologize.	1	MR. ANDERSON: Yeah. But your version is
2	BY MR. THOMAS:	2	different from this version because you've got
3	Q. The purpose of this article,	3	yours stamped at the bottom.
4	Plaintiff's 2071, is to review the state of science	4	THE WITNESS: Do you have the pages?
5	and medicine on the mesh concept known as lightweight	5	MR. ANDERSON: And we don't have the stamped.
6	and large porous for hernia repair?	6	THE WITNESS: We don't have the same pages.
7	A. Yes, that is	7	MR. THOMAS: I'll do it from your document.
8	Q. Thank you.	8	Let me see if I can find the page. I wonder why
9	A true.	9	it's different.
10	Q. And in here you talk not only about old	10	BY MR. THOMAS:
11	meshes but also new meshes; correct?	11	Q. Let's go to page 10 of Exhibit 0271, please.
12	A. The new generation mesh, yeah.	12	Do you have page 10?
13	Q. And in the abstract, which is on the first	13	A. Yes.
14	page of 2071, you state that: "All experimental	14	Q. On page 10 you and your coauthors begin
15	evidence and first clinical data indicate the	15	talking about the new generation of lightweight large
16	superiority of the lightweight large porous mesh	16	porous meshes, Vypro and Vypro II; correct?
17	concept with regard to a reduced number of long-term	17	A. Yes.
18	complications and particularly increased comfort and	18	Q. And is the purpose of this discussion to talk
19	quality of life after hernia repair."	19	about the promise of Vypro and Vypro II in hernia
20	Correct?	20	repair; correct?
21	A. That is correct.	21	A. The purpose of what?
22	Q. And what you're referring to there are your	22	Q. The promise.
23	initial results; correct?	23	A. Promise?
24	A. What is your definition of "initial"?	24	Q. The future potential benefits of Vypro let
1	Q. Well, there's certainly	1	me ask the question again.
2	A. It is what we know to this time point.	2	On page 10 of Exhibit 0271, there is a
3	Q. There are no long-term studies available to	3	paragraph titled "The New Generation: Lightweight
4	determine the extent to which lightweight large pore	4	Large Porous Meshes." Correct?
5	mesh behaves better than small pore heavyweight mesh,	5	A. Yes.
6	as you've described them in this study, at the time	6	Q. And in that paragraph, series of paragraphs,
7	that you published this study?	7	you discuss Vypro and Vypro II?
8	A. At this time, no, not to my knowledge.	8	A. Yes.
9	Q. Okay. Let's go to page 112, please.	9	Q. And those Vypro I is the mesh that you
10	I don't think that's the right page, Doctor.	10	helped develop with Ethicon for hernia repair;
11	112.	11	correct?
12	MR. ANDERSON: 112?	12	A. Yes.
13	MR. THOMAS: Under	13	Q. And Vypro II was a subsequent development of
14	MR. ANDERSON: You're reading off of your	14	Vypro again in hernia repair; correct?
15	exhibit number, but you said go to Plaintiff's	15	A. Yes.
16	Exhibit, so ours doesn't have your do you have	16	Q. And the bottom of that paragraph or that
17	your trial exhibit number?	17	section says that, "First clinical trials confirm the
18	MR. THOMAS: I'm looking at this number right	18	expected superiority of the lightweight large porous
19	here, 112. Is that different than yours?	19	mesh concept concerning quality of life after hernia
20	MR. ANDERSON: Yeah. Maybe yours is	20	repairs."
21	different. Let's see. Did you did you give	21	What does "quality of life after hernia
22	me your exhibit?	22	repair" mean?
23	MR. THOMAS: You already it's already in	23	A. It depends from the from the trial that
	the record, so I didn't.	24	you are doing. Quality of life to measure quality
24			

40 (Pages 154 to 157)

	Page 158		Page 160
1	of life, there are different tools depending on the	1	it is not possible at all to do this confirmation at
2	investigator. It can be looking to foreign body	2	clinical studies.
3	sensation. It can be looking to pain. It can be	3	Q. At the time that you published Exhibit 2075,
4	looking to serious complications. So a lot of these	4	there were no clinical trials available to confirm
5	things. And there are some attempts to quantify	5	the promising preclinical results of the lightweight
6	them. There are some questionnaires, as SF-36, which	6	large porous polypropylene mesh that most
7	gives a lot of data. So you try to quantify quality	7	manufacturers have added; correct?
8	of life to know what happens to the patient.	8	A. So it is correct
9	Q. Okay. And is the quality of life an	9	Q. Thank you.
10	appropriate end point for a study to determine	10	A in regard to comparing studies.
11	whether a mesh implanted in the body is functioning	11	Q. Okay.
12	appropriately?	12	A. It is not correct in regards to the analysis
13	A. It's usually a secondary end point. It's	13	of explants.
14	Q. Secondary to recurrence?	14	MR. THOMAS: All right. Move to strike
15	A. Yes.	15	everything after "it's correct."
16	Q. Okay.	16	BY MR. THOMAS:
17	A. Usually.	17	Q. You also discuss on page 11 of Exhibit 0271
18	Q. All right. But it's an important end point	18	Ultrapro; correct?
19	to understand how a patient's quality of life has	19	A. Yes.
20	been affected by the hernia repair; correct?	20	Q. And Ultrapro is the mesh that you understand
21	A. It's one way to measure this.	21	to be the predominant mesh used in hernia repair in
22	Q. And at this time there are no long-term	22	Germany; is that correct?
23	studies on Vypro and Vypro II to determine the	23	A. So far I know, yes.
24	quality of life for these patients after hernia	24	Q. And at the end of your discussion of
	Page 159		Page 161
1	Page 159 repair; true?	1	
1 2		1 2	Page 161 Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the
	repair; true?		Ultrapro, you say, "Overall the Monocryl
2	repair; true? A. So far I remember the long term is there one,	2	Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the
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2 3 4 5	repair; true? A. So far I remember the long term is there one, two years maybe. I don't know exactly the Brinkman study when it came up, when it was published there. It was about three years, so it depends from what you	2 3 4 5	Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the member of the lightweight large porous mesh family with the lowest foreign body reaction and optimized handling. The first clinical studies produced
2 3 4 5 6	repair; true? A. So far I remember the long term is there one, two years maybe. I don't know exactly the Brinkman study when it came up, when it was published there. It was about three years, so it depends from what you are thinking of long term. Q. And under polypropylene, next paragraph down, you say, "Most manufacturers have added to their	2 3 4 5 6	Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the member of the lightweight large porous mesh family with the lowest foreign body reaction and optimized handling. The first clinical studies produced encouraging results to move forward with this mesh
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	repair; true? A. So far I remember the long term is there one, two years maybe. I don't know exactly the Brinkman study when it came up, when it was published there. It was about three years, so it depends from what you are thinking of long term. Q. And under polypropylene, next paragraph down, you say, "Most manufacturers have added to their range of polypropylene heavyweight mesh small porous mesh modifications, lightweight large porous adaptation." Correct? Did I read that correctly? A. Yeah. Yes. Q. And if you go to the last sentence in that section it says, "However, clinical trials have yet to confirm the promising preclinical results." Now, what does that mean? A. That means that at that time we hoped that it is possible to make the clinical trial and to demonstrate that one material is superior to another just by operating 150 patients in this direction or and 150 patients with another mesh, and we did some prospective clinical trials with Ethicon	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23	Ultrapro, you say, "Overall the Monocryl polypropylene composite Ultrapro is currently the member of the lightweight large porous mesh family with the lowest foreign body reaction and optimized handling. The first clinical studies produced encouraging results to move forward with this mesh concept." Correct? A. Yes. Q. And I believe you've already told me that you do not think that Ultrapro strike that. Ultrapro is the same mesh as Prolift+M; correct? A. Prolift+M used the Ultrapro. Q. Okay. And you do not believe that Ultrapro, known as Prolift+M, is appropriate for use in the pelvic floor; correct? A. This work is focused on the tension-free situation in the abdominal wall without applying any forces to it. At that time we didn't think that someone is using this mesh for a situation where you applied some forces; and, therefore, Ultrapro is still the mesh I think with the largest pores and,
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41 (Pages 158 to 161)

Page 164 Page 162 Q. You answered my question no, so I need to 1 applied without any force and tension and if it's 1 2 laying flat. 2 answer it again -- ask it again. 3 3 It's true that you have never designed a mesh Q. Is it your opinion that Ultrapro should not 4 be used for abdominal hernia repair? 4 for the treatment of pelvic organ prolapse; true? 5 A. For abdominal hernia repair there is, of 5 A. I was involved in the design process in 6 course, an indication to use it. 6 regards to the question whether the textile design 7 7 Q. Okay. And so is it your opinion that fulfills these requirements, but, of course, I'm not 8 Ultrapro is appropriate for abdominal hernia repair, 8 entirely manufacturing or designing meshes for the 9 9 but the same mesh in Ultrapro, which is in Prolift+M, pelvic floor. 10 is not appropriate in the pelvic floor? 10 Q. And can you identify for me any mesh A. It doesn't matter in what tissue you are 11 available in the United States today that is -- where 11 12 12 the benefits outweigh the risk for the treatment of using it. It is -- you should use it in a 13 13 tension-free way so that it's laying as an area, as a pelvic organ prolapse? 14 flat mesh there. If you apply some tension -- and we 14 A. You cannot answer this question because it's 15 made ourselves experiments using the Ultrapro close 15 a general statement. It doesn't make any sense. 16 to the diaphragma where we applied some tension to it 16 Q. Okay. Since the work that you've done --17 and got disappointing results with the Ultrapro. So 17 strike that. 18 it depends on the specific indication function of 18 Since your 2005 article that you've just 19 these devices. 19 described, there have been long-term studies 20 Q. And surgical technique? 20 comparing lightweight large pore mesh against small 21 21 A. If you are free -- if you are free, of pore heavyweight mesh, haven't there? 22 course, with the surgical technique you can do every 22 A. There has been published several studies, 23 complication that is imaginable, but there are some 23 yeah. 24 procedures that need some forces, and in these cases 24 Page 163 Page 165 1 this mesh is not a good alternative. It's not a safe 1 (Klinge Trial Deposition Exhibit No. 5, 2 alternative. 2 Article entitled "Long-term outcome and quality of 3 3 Q. And when you speak about "this mesh," you're life after open incisional hernia repair - light 4 talking about Ultrapro? 4 versus heavyweight meshes", was marked for 5 5 A. Ultrapro. identification.) 6 Q. Okay. 6 7 7 BY MR. THOMAS: A. Yeah, you talk. 8 8 Q. Is there any mesh that you've identified Q. Let me show you what's been marked as Klinge 9 that's appropriate for use in the pelvic floor for 9 Trial Exhibit Number 5. It's a research article 10 the repair of pelvic organ prolapse? 10 titled "Long-Term Outcome and Quality of Life After 11 A. I cannot give a general statement to this. I Open Incisional Hernia Repair, Light Versus 11 12 know that there are textile constructions and design 12 Heavyweight Meshes." First author is Ladurner. Have 13 for meshes that are more resistant to the collapse, 13 you seen this study? 14 but it depends on the indication of the specific 14 A. I guess I have seen it, yeah. 15 situation. There is never one device for all 15 Q. And this is a long-term study of up to 72 16 diseases in the pelvic floor. No, it's not done. It 16 months after incisional hernia repair with 17 has to be very carefully designed for the specific 17 lightweight meshes compared to heavyweight meshes; 18 purpose. 18 correct? 19 Q. And you've not designed a specific mesh for 19 A. Yeah. 20 the treatment of pelvic organ prolapse; true? 20 Q. And the heavyweight mesh is a Prolene mesh. 21 A. No. I'm only asked sometimes whether this 21 The lightweight mesh is your Vypro mesh; correct? 22 fits our -- whether the device of the FEG, where I am 22 A. Yes. 23 a consultant, fits to these principles of less 23 Q. And the two groups were equal in body mass 24 material, large pores and stability of the structure. 24 index, age, gender and hernia size; correct?

	Page 166		Page 168
1	Is that correct?	1	this conclusion; and it is not justified. And the
2	A. Age and gender you said?	2	statistical power is just one measure. Yeah, you
3	Q. If you look in the abstract, see in the	3	have to consider this. It's not because I want to
4	abstract?	4	have it.
5	A. Yeah.	5	Q. Let's
6	Q. It says right in the middle under "Methods,"	6	A. And, therefore, it is so difficult to make a
7	"The two groups were equal in BMI," which is body	7	clinical trial comparing two different devices in
8	mass index, "age, gender and hernia size." Correct?	8	similar patients.
9	A. Yeah. I'm looking to the data there, so	9	Q. Let's
10	hernia size almost it's yeah.	10	A. And, therefore, we need as an alternative
11	Q. Okay. And it finds in the conclusions, "In	11	registry. Yes, I'm sure.
12	this study the health-related quality of life based	12	Q. Registries is the better way to go?
13	upon FS36 survey after open incisional hernia repair	13	A. It offers the option to accumulate data from
14	with light or heavyweight meshes is not related to	14	a long of very many patients over a long period,
15	the mesh type in the long-term follow-up."	15	and, of course, the data of the registries over the
16	Did I read that correctly?	16	time will help us to understand it.
17	A. You read this correctly.	17	MR. THOMAS: Let's take a break and change
18	Q. And what that means is that the kind of mesh	18	the tape.
19	that was used in the hernia repair did not affect the	19	THE VIDEOGRAPHER: We are off the record.
20	long-term quality of life in the patients in this	20	The time is 12:21 p.m.
21	study; true?	21	(A recess was taken from 12:21 p.m. until 12:33 p.m.)
22	A. No. Because it is ridiculous to take this	22	THE VIDEOGRAPHER: This marks beginning of
23	study with 12 patients in one group and 12 patients	23	Video Number 3. We are back on the record. The
24	in the other and to make a read out with the FS36.	24	time is 12:33 p.m.
	Page 167		Page 169
1	It is so tremendously underpowered that this	1	BY MR. THOMAS:
2	It is so tremendously underpowered that this statement, of course, is not confirmed by these data.	2	BY MR. THOMAS: Q. Doctor, before we were broke, we were
2	It is so tremendously underpowered that this statement, of course, is not confirmed by these data. It's ridiculous to discuss this.	2	BY MR. THOMAS: Q. Doctor, before we were broke, we were talking about the limitations in randomized
2 3 4	It is so tremendously underpowered that this statement, of course, is not confirmed by these data. It's ridiculous to discuss this. Q. Well, it's certainly what this study reports;	2 3 4	BY MR. THOMAS: Q. Doctor, before we were broke, we were talking about the limitations in randomized controlled trials, about them not being sufficiently
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Page 170 Page 172 A. So registries should be done additionally to 1 randomized controlled trials and meta-analyses; 1 2 2 randomized controlled trials depending on the 3 3 A. I showed the limitation of these -question, depending on the setting. 4 Q. Yes. 4 Q. And registries, just for the benefit of the 5 A. -- or some questions. 5 jury, are sets of data that are accumulated as people 6 Q. And the ultimate conclusion of this paper, 6 go through hernia surgeries, and data is completed at 7 7 Klinge Trial Exhibit Number 6, is that registries the time of the surgery; correct? 8 provide better information than do randomized 8 A. The data are not complete yet. Registries 9 have the advantage that you can include various kinds 9 controlled trials or meta-analyses; correct? 10 A. Not correct. If you believe that better is 10 of patients, not only restricted to some standard 11 11 patients, and you can include a follow-up of various sufficient than -- that is not the purpose to have 12 12 times, very long period. There is -- in clinical better data, but we need other data, and registries 13 13 studies, you usually finish after one day or one year are able to provide additional data that will help us 14 to define what is the outcome of the patients, yes, 14 or two years. So the registry offers a lot of more 15 15 additionally. options to made a post-market surveillance quality 16 16 Q. Go to page 787 of Trial Exhibit Number 6. control of devices; and, therefore, I think it is 17 You see that? You see in the middle of the 17 very interesting from manufacturer if they are 18 second paragraph it begins, "Observational studies 18 interested in making their follow-up of their 19 nowadays can best be done with the help of 19 patients. Q. Okay. Let me show you what's been marked as 20 registries, would provide a structure and a set of 20 21 21 variables that are known to reflect all major Klinge Trial Exhibit Number 6. 22 influences on the patients' outcome. In this regard, 22 THE COURT REPORTER: It should be 7. 23 it uses the same variables as the RSCT but did not 23 MR. THOMAS: Seven. I'm sorry. Let me mark 24 restrict its data acquisition to a small group of 24 on it 7. Let me have that back, Doctor, please. Page 171 Page 173 study patients." 1 1 2 Did I read that correctly? 2 (Klinge Trial Exhibit No. 7, Article entitled 3 A. Yes. 3 "Prospective, Long-Term Comparison of Quality of Life 4 Q. And the purpose of that is to talk about more 4 in Laparoscopic Versus Open Ventral Hernia Repair", 5 5 robust data set from a greater number of people? was marked for identification.) 6 MR. ANDERSON: Objection. RSCTs are outside 6 7 7 BY MR. THOMAS: the scope of direct. 8 8 But go ahead, Dr. Klinge. Q. Doctor, let me show you what I have marked 9 THE WITNESS: So I'm not sure whether it's 9 now as Klinge Trial Exhibit Number 7. 10 10 possible to reduce robust database, whether this Klinge Trial Exhibit Number 7 is a 2012 11 covers all the questions that we address in this 11 study, first author Colavita, titled "Prospective, 12 12 article. Long-Term Comparison of Quality of Life in 13 BY MR. THOMAS: 13 Laparoscopic Versus Open Ventral Hernia Repair." 14 Q. Do you conclude from this article that using 14 Have you seen this before? 15 15 data from a long-term registry with a large number of A. I have seen it, but it's some time ago. 16 patients with more data is better than doing the 16 Q. Okay. And if you look down at the methods, 17 randomized controlled trials that have been used in 17 patients in this study were drawn from the the past? international hernia registry; correct? 18 18 19 A. I would never say that it is better in a 19 A. Yes. 20 20 general term. It will help us to define the outcome Q. And it's 30 centers in the United States, 21 21 Canada and Europe and Australia; correct? of the patients, better than in -- with all the 22 limitations of randomized controlled trials, and this 22 A. Yes. 23 is expressed on several pages there. 23 Q. And in this study the authors looked at a 24 total of 710 hernia repairs; correct? 24 Q. Okay.

44 (Pages 170 to 173)

	Page 174		Page 176
1	A. Yes.	1	study, first full paragraph on the left, it says, "In
2	Q. And looked at the long-term comparison of	2	multivariant analysis, mesh weight had no effect on
3	quality of life for these 710 hernia repairs;	3	pain, activity limitation, mesh sensation, or overall
4	correct?	4	symptoms in the present study."
5	A. Yes.	5	Did I read that correctly?
6	Q. And they used what's known as the Carolinas	6	A. You read this correctly.
7	Comfort Scale. Are you familiar with that?	7	Q. And it follows down to the end of that
8	A. Yes, I know it.	8	paragraph and it says, "In a recent small comparative
9	Q. And that's is that similar to the SF-36	9	study of open ventral hernia repair with light and
10	questionnaire that we talked about in the previous	10	heavyweight mesh, no difference was seen in quality
11	study?	11	of life using SF-36 with long-term follow-up."
12	A. It is another tool.	12	And that's the study that we looked at a
13	Q. Okay. Do you recognize the Carolinas Comfort	13	minute ago, the Ladurner study; correct?
14	Scale as a way to determine the quality of life in a	14	A. Twenty-seven, if this is here, the reference,
15	population of patients?	15	27? Yeah, you're right.
16	A. It is a way to measure it, yeah.	16	Q. The results of this study, Klinge Exhibit 7,
17	Q. Okay. At the time this study was published	17	confirms these findings this long-term study from
18	in 2012, if you look at the first page under the	18	the registry, Klinge Exhibit Number 7, confirms the
19	abstract and conclusion, to your knowledge was this	19	randomized controlled trials, the Ladurner study,
20	the largest prospective quality of life study	20	that we talked about before. That's what this study
21	comparing laparoscopic ventral hernia repair with	21	finds; correct?
22	open ventral hernia repair, or do you know?	22	A. It confirms that the insufficiency of this
23	A. I think that's that is true.	23	study to detect any differences. It is not possible
24	Q. Okay. And so what these authors did was go	24	to prove something by doing these studies, and,
	Page 175		Page 177
1	Page 175 to the registry and get the data that you have just	1	Page 177 therefore, there is a tremendous flaw in the
1 2		1 2	
	to the registry and get the data that you have just		therefore, there is a tremendous flaw in the
2	to the registry and get the data that you have just described in your previous answers in order to make	2	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to
2	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data	2	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's
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2 3 4 5 6 7 8	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true? A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me. Q. If you go to page 719 of Klinge Trial Exhibit	2 3 4 5 6 7 8	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's A. Even if it's done and even if it's published, no. Q. So you disagree with the findings in Klinge Exhibit Number Trial Exhibit Number 7? A. The interpretation, yeah. It's completely
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true? A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me. Q. If you go to page 719 of Klinge Trial Exhibit Number 7, first paragraph on the left, midway down, the authors conclude from this study, "There was no difference in mesh sensation symptoms between heavyweight or lightweight polypropylene mesh. As mentioned earlier, both were used with similar frequency and laparoscopic and open repairs." Did I read that correctly? A. Yes. Q. So across this population of 710 hernia repairs, comparing lightweight mesh as opposed to	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's A. Even if it's done and even if it's published, no. Q. So you disagree with the findings in Klinge Exhibit Number Trial Exhibit Number 7? A. The interpretation, yeah. It's completely not justified. Q. Now, Dr. Klinge, you have contended for years that traditional use of hernia repair are overengineered excuse me. Start over again. Strike that. Doctor, you have contended for years that traditional meshes used for hernia repair are overengineered and is stronger than is necessary for the treatment of hernia repair; correct? A. We found this, yeah.
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true? A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me. Q. If you go to page 719 of Klinge Trial Exhibit Number 7, first paragraph on the left, midway down, the authors conclude from this study, "There was no difference in mesh sensation symptoms between heavyweight or lightweight polypropylene mesh. As mentioned earlier, both were used with similar frequency and laparoscopic and open repairs." Did I read that correctly? A. Yes. Q. So across this population of 710 hernia repairs, comparing lightweight mesh as opposed to heavyweight mesh, they found no difference as to mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's A. Even if it's done and even if it's published, no. Q. So you disagree with the findings in Klinge Exhibit Number Trial Exhibit Number 7? A. The interpretation, yeah. It's completely not justified. Q. Now, Dr. Klinge, you have contended for years that traditional use of hernia repair are overengineered excuse me. Start over again. Strike that. Doctor, you have contended for years that traditional meshes used for hernia repair are overengineered and is stronger than is necessary for the treatment of hernia repair; correct? A. We found this, yeah. Q. And you have argued that a lighter weight
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true? A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me. Q. If you go to page 719 of Klinge Trial Exhibit Number 7, first paragraph on the left, midway down, the authors conclude from this study, "There was no difference in mesh sensation symptoms between heavyweight or lightweight polypropylene mesh. As mentioned earlier, both were used with similar frequency and laparoscopic and open repairs." Did I read that correctly? A. Yes. Q. So across this population of 710 hernia repairs, comparing lightweight mesh as opposed to heavyweight mesh, they found no difference as to mesh sensation; correct? Is that correct?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's A. Even if it's done and even if it's published, no. Q. So you disagree with the findings in Klinge Exhibit Number Trial Exhibit Number 7? A. The interpretation, yeah. It's completely not justified. Q. Now, Dr. Klinge, you have contended for years that traditional use of hernia repair are overengineered excuse me. Start over again. Strike that. Doctor, you have contended for years that traditional meshes used for hernia repair are overengineered and is stronger than is necessary for the treatment of hernia repair; correct? A. We found this, yeah. Q. And you have argued that a lighter weight larger pore mesh is better to accomplish the same
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	to the registry and get the data that you have just described in your previous answers in order to make their analysis of a bigger population with more data for their findings; true? A. They are going to a registry, but the registry is not only registry because it has name. You have to go into the details, look at what variables are recorded. That was outlined in the previous paper for me. Q. If you go to page 719 of Klinge Trial Exhibit Number 7, first paragraph on the left, midway down, the authors conclude from this study, "There was no difference in mesh sensation symptoms between heavyweight or lightweight polypropylene mesh. As mentioned earlier, both were used with similar frequency and laparoscopic and open repairs." Did I read that correctly? A. Yes. Q. So across this population of 710 hernia repairs, comparing lightweight mesh as opposed to heavyweight mesh, they found no difference as to mesh	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	therefore, there is a tremendous flaw in the interpretation of these data. You are not allowed to say that this study proves that result is similar. It is it is not justified to do so. Q. Okay. Let's A. Even if it's done and even if it's published, no. Q. So you disagree with the findings in Klinge Exhibit Number Trial Exhibit Number 7? A. The interpretation, yeah. It's completely not justified. Q. Now, Dr. Klinge, you have contended for years that traditional use of hernia repair are overengineered excuse me. Start over again. Strike that. Doctor, you have contended for years that traditional meshes used for hernia repair are overengineered and is stronger than is necessary for the treatment of hernia repair; correct? A. We found this, yeah. Q. And you have argued that a lighter weight

	Page 178		Page 180
1	Q. Yes.	1	Q. And that's the mesh that you helped develop
2	A. I didn't get every word of your question.	2	with Ethicon?
3	Q. Let me ask it again.	3	A. Yes, with a pore size of 3 to 5 millimeter.
4	A. Yes.	4	Q. And you compared Vypro against the
5	Q. You have contended that a manufacturer can	5	heavyweight monofilament Marlex; correct?
6	design a lighter weight larger pore mesh to	6	A. In this article we took Marlex
7	accomplish the same repair of a hernia as you can	7	Q. Correct.
8	with a traditional heavyweight mesh; correct?	8	A as an example of a small pore mesh.
9	A. No.	9	Q. And the Marlex pore size is not the same as
10	Q. What did I miss? You can't get the same	10	the Prolene Soft pore size, is it?
11	repair with a lighter weight larger pore mesh?	11	A. There are differences.
12	A. If you're believing that you can exactly the	12	Q. Yes. The Marlex mesh is typically reported
13	same type of repairs with a heavyweight mesh and a	13	as a 0.6 millimeter mesh, isn't it?
14	large pore lightweight meshes, no, that's not true.	14	A. Roughly it is assumed that it has smaller
15	There are indications for the different meshes.	15	pores.
16	Q. Still appropriate	16	Q. And the Prolene Soft Mesh is typically
17	A. What we said is that you can improve the	17	described as a mesh with about 2.5 millimeters;
18	tissue integration by reduction of the material,	18	correct?
19	making the pores larger, and that therefore, we	19	A. I don't want to say that it is possible to
20	developed together with Ethicon these large pore	20	reflect the pore size just by one figure. You know
21	meshes, and this was confirmed in many animal trials,	21	all the limitations of all these techniques, yeah.
22	human explants.	22	Q. They are certainly different, aren't they?
23	Q. Let's go back to P1087, please.	23	The Marlex and the Prolene Soft Mesh are very
24	MR. ANDERSON: Did you say 1087?	24	different in their characteristics?
	Dama 170		Dama 101
	Page 179		Page 181
1	MR. THOMAS: Yes. It's the PowerPoint.	1	A. Yes. The soft Prolene mesh is more open than
2	MR. ANDERSON: I know. We just have a stack	2	the Marlex.
3	of documents, so I have to find it.	3	Q. Okay. Doctor, you cannot point to a mesh
4	MR. THOMAS: Strike that. I'm not going to	4	today for use in the pelvic floor that has no risks
5	do that one anyway.	5	of infection, can you?
6	MR. ANDERSON: Okay.	6	A. There is no study if you no risks means
7	MR. THOMAS: Let's go to P0260, which is a	7	no complication at all? No, there is no way.
8	2002 study with Dr. Klinge and Dr. Klosterhalfen.	8	MR. ANDERSON: I'll just say objection;
9	MR. ANDERSON: Okay.	9	outside the scope of direct.
10	BY MR. THOMAS:	10	BY MR. THOMAS:
11	Q. Doctor, on direct examination you discussed	11	Q. And, Doctor, you do not know of any mesh construction that leads to a lower strike that.
12	Plaintiff's Exhibit 0260 in connection with your	13	
13	earlier work on talking about the impact of polymer		Doctor, you do not know of any mesh
14	pore size on the interface scar formation in a rat	14	construction for use in the pelvic floor that leads
15	model; correct? A. That is correct.	15 16	to a lower erosion rate than Prolift; correct? A. I know that there are that there are ways
16		17	to reduce the risk. There are no clinical
17	Q. And you used this article to talk about your		
18	findings about what happens with the smaller pore	18 19	comparative studies, to my knowledge.
19	heavyweight mesh, correct, as compared to the		Q. Doctor, you know of you do not know of any
20	heavyweight large pore mesh? A. Yes.	20	mesh construction today for use in the pelvic floor that leads to a lower erosion rate than Prolift;
21 22		21 22	correct?
23	Q. And in this study, the lightweight large pore mesh that you use as a comparator is your Vypro mesh?	23	MR. ANDERSON: Objection; asked and answered.
	mesh mat you use as a comparator is your yydro mesh?	L 43	with Airobitson. Objection, asked and answered.
23	A. Yes.	24	THE WITNESS: A mesh construction which

46 (Pages 178 to 181)

	Page 182		Page 184
1	follows our criteria reducing the material,	1	A. No comparative studies are available, to my
2	making it larger, it will reduce the erosion	2	knowledge.
3	rate, but there is no comparative study	3	Q. Okay. Can you name one mesh on the market
4	available.	4	today that you think that the benefits outweigh the
5	BY MR. THOMAS:	5	risks for use in treatment of pelvic organ prolapse?
6	Q. Let me ask the question again, Doctor.	6	A. No. And to answer this question, it is
7	Are you aware of any mesh construction for	7	impossible in this general statement. It depends on
8	use in the pelvic floor that leads strike that.	8	the patient. It depends on the indication. Then you
9	Are you aware of any mesh constructions	9	have to specify which implant under which conditions.
10	available for use today in the pelvic floor that	10	So it is not possible to answer this question.
11	leads to lower erosion rates than Prolift?	11	MR. THOMAS: Let's take a break for a second.
12	MR. ANDERSON: Objection; asked and answered	12	THE VIDEOGRAPHER: We are off the record.
13	for the third time.	13	The time is 12:55 p.m.
14	THE WITNESS: As I don't know any comparative	14	(A recess was taken from 12:55 p.m. until 1:00 p.m.)
15	study directly comparing different mesh	15	THE VIDEOGRAPHER: We are back on the record.
16	structures, I only can say that there are mesh	16	The time is 1:00 p.m.
17	structures with lower risk than the Prolift.	17	BY MR. THOMAS:
18	BY MR. THOMAS:	18	Q. Doctor, can you tell the jury one product on
19	Q. But you are	19	the market for the treatment of pelvic organ prolapse
20	A. For erosion.	20	that you think is better than the Prolift?
21	Q. But you are aware of no studies that prove	21	A. In regard to the effective porosity, for
22	that point; correct?	22	example, and the strain, I know that DynaMesh has a
23	A. No clinical studies proving this.	23	device that is superior to the Prolift.
24	Q. Is that true?	24	Q. And the DynaMesh is not is that the only
	Page 183		Page 185
1	A. That is true.	1	one that you think is better for use in the pelvic
2	Q. Okay. And you are aware of no mesh	2	floor
3	construction that causes less chronic pain in the	3	A. I know
4	pelvic floor than Prolift; true?	4	O than the Prolift?
5			
_	A. No clinical study comparing different mesh	5	A. I know there is a huge variety. I'm not sure
6	A. No clinical study comparing different mesh materials and showing differences are available up to	5 6	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I
	materials and showing differences are available up to now.	1	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we
6	materials and showing differences are available up to	6	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I
6 7	materials and showing differences are available up to now.	6 7	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we
6 7 8	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in	6 7 8	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that
6 7 8 9	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture	6 7 8 9	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market.
6 7 8 9 10	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true?	6 7 8 9 10	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in
6 7 8 9 10 11	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh	6 7 8 9 10 11	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct?
6 7 8 9 10 11	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it,	6 7 8 9 10 11 12	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the
6 7 8 9 10 11 12	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse.	6 7 8 9 10 11 12 13	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available?
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6 7 8 9 10 11 12 13 14 15	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available	6 7 8 9 10 11 12 13 14 15	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find.
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6 7 8 9 10 11 12 13 14 15 16	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift?	6 7 8 9 10 11 12 13 14 15 16	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find. Go ahead. THE WITNESS: I think it is not available,
6 7 8 9 10 11 12 13 14 15 16 17	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift? A. There are mesh constructions which are closer	6 7 8 9 10 11 12 13 14 15 16 17 18	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find. Go ahead. THE WITNESS: I think it is not available, but I'm not knowing all the details which product
6 7 8 9 10 11 12 13 14 15 16 17 18	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift? A. There are mesh constructions which are closer to these criteria for mesh design for safe mesh	6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find. Go ahead. THE WITNESS: I think it is not available, but I'm not knowing all the details which product is in which country on the market.
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift? A. There are mesh constructions which are closer to these criteria for mesh design for safe mesh design.	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find. Go ahead. THE WITNESS: I think it is not available, but I'm not knowing all the details which product is in which country on the market. BY MR. THOMAS:
6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	materials and showing differences are available up to now. Q. And you're aware of no mesh design for use in the pelvic floor that provides lower contracture rates than the Prolift; true? A. No, that's not true. I'm well-aware of mesh criteria for a safer mesh design as we outlined it, less material, larger pores and no pore collapse. This will make a safer mesh design. Q. Are you aware of any mesh design available for use today in the pelvic floor that provides lower contraction rates than the Prolift? A. There are mesh constructions which are closer to these criteria for mesh design for safe mesh design. Q. Are you aware of any comparative studies	6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. I know there is a huge variety. I'm not sure which is what is on the market, actually, but I know that there are various designs of meshes; but we didn't make a systematic testing of all devices that are on the market or have been on the market. Q. And the DynaMesh is not available for sale in the United States; correct? A. I think so, but I'm not informed about the Q. You think that it is available? MR. ANDERSON: Let him finish his answer, if you wouldn't find. Go ahead. THE WITNESS: I think it is not available, but I'm not knowing all the details which product is in which country on the market. BY MR. THOMAS: Q. Let me

	Page 186		Page 188
1	You don't know whether DynaMesh, manufactured	1	A. I don't have an own at the moment I don't
2	by FEG, is available for sale in the United States,	2	have an own collection of pelvic floor meshes.
3	do you?	3	Q. You collect hernia meshes; correct?
4	A. I don't know.	4	A. We had collected, but meanwhile the all
5	Q. Okay. And you said that DynaMesh is better	5	the tissue samples are stored in a biotissue bank
6	than Prolift from the perspective of effective	6	from the university from the institute for pathology
7	porosity?	7	centrally where they are stored under GCP conditions.
8	A. As we measure it, as we can show with our	8	Q. Okay. But you've never asked your department
9	measurements it has a higher effective porosity, it	9	that deals with the pelvic floor to preserve and
10	has a higher stability when put to strain.	10	collect meshes that have been removed in explants;
11	Q. But you agree that there are no clinical	11	correct?
12	long-term studies that prove the superiority of the	12	A. No. It's no longer an issue that I that
13	DynaMesh over the Prolift for the treatment of pelvic	13	I'm asked to collect these. They are sent all to
14	organ prolapse?	14	this bio bank; and when you want to make a research,
15	A. There are at all no comparative studies	15	then you can ask for getting these samples.
16	showing the superiority of any of these, and, again,	16	Q. Now, to your knowledge, there's only one mesh
17	it is not possible to do so. I don't see a good way	17	manufacturer in the world that makes mesh made of
18	to do so.	18	PVDF for the treatment of pelvic organ prolapse;
19	Q. And you're aware of no studies that	19	correct?
20	demonstrate that PVDF mesh, which is DynaMesh, is	20	A. In the moment, I think this is true.
21	superior to the polypropylene mesh used in Prolift;	21	Q. And that's FEG?
22	correct?	22	A. This is true.
23	A. We know from many histological studies that	23	Q. And that's the German mesh manufacturer
24	the tissue reaction to PVDF is better than the tissue	24	headquartered here in Aachen?
			Page 189
1	reaction to the polypropylene, less inflammation,	1	A. Yes.
2	less scarring when you are using the PVDF.	2	Q. And you helped PVDF excuse me. Strike
3	Q. And the PVDF strike that.	3	that.
4	You're aware of no studies in humans that	4	You helped FEG develop its PVDF mesh, didn't
5	demonstrate that PVDF mesh is superior to	5	you?
6	polypropylene mesh used in Prolift for pelvic floor	6	A. Yes.
7	repair; correct?	7	Q. And you're named on the patent for PVDF mesh?
8	A. Our studies in human explants always	8	A. Yes.
9	confirmed the superiority of PVDF as a polymer to be	9	Q. You've done research for FEG since 1994;
10	integrated in tissue.	10	correct?
	_	I	
11	Q. And is this in hernia explants?	11	A. That is correct.
11 12	Q. And is this in hernia explants?A. This is in hernia explants.	11 12	A. That is correct.Q. And Dr. Oberlinski is one of FEG's owners;
12	A. This is in hernia explants.	12	Q. And Dr. Oberlinski is one of FEG's owners;
12 13	A. This is in hernia explants.Q. And these this is the hernia explants that	12 13	Q. And Dr. Oberlinski is one of FEG's owners; correct?
12 13 14	A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his	12 13 14	Q. And Dr. Oberlinski is one of FEG's owners;correct?A. That is correct.
12 13 14 15	A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection?	12 13 14 15	Q. And Dr. Oberlinski is one of FEG's owners; correct?A. That is correct.Q. And he used to work with you at the
12 13 14 15 16	A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes.	12 13 14 15 16	Q. And Dr. Oberlinski is one of FEG's owners; correct?A. That is correct.Q. And he used to work with you at the university; correct?
12 13 14 15 16 17	 A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes. Q. And have you looked at any PVDF mesh explants 	12 13 14 15 16 17	 Q. And Dr. Oberlinski is one of FEG's owners; correct? A. That is correct. Q. And he used to work with you at the university; correct? A. This again? Q. He used to work Dr. Oberlinski used to
12 13 14 15 16 17 18	 A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes. Q. And have you looked at any PVDF mesh explants from the pelvic floor? 	12 13 14 15 16 17 18	Q. And Dr. Oberlinski is one of FEG's owners; correct?A. That is correct.Q. And he used to work with you at the university; correct?A. This again?
12 13 14 15 16 17 18	 A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes. Q. And have you looked at any PVDF mesh explants from the pelvic floor? A. Up to now I never saw one. 	12 13 14 15 16 17 18 19	 Q. And Dr. Oberlinski is one of FEG's owners; correct? A. That is correct. Q. And he used to work with you at the university; correct? A. This again? Q. He used to work Dr. Oberlinski used to work at the university, didn't he?
12 13 14 15 16 17 18 19 20	 A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes. Q. And have you looked at any PVDF mesh explants from the pelvic floor? A. Up to now I never saw one. Q. Okay. 	12 13 14 15 16 17 18 19 20	 Q. And Dr. Oberlinski is one of FEG's owners; correct? A. That is correct. Q. And he used to work with you at the university; correct? A. This again? Q. He used to work Dr. Oberlinski used to work at the university, didn't he? A. When we started our collaboration, he worked
12 13 14 15 16 17 18 19 20 21	 A. This is in hernia explants. Q. And these this is the hernia explants that you've reviewed with Dr. Klosterhalfen in his collection? A. Yes. Q. And have you looked at any PVDF mesh explants from the pelvic floor? A. Up to now I never saw one. Q. Okay. A. Which is a good sign. 	12 13 14 15 16 17 18 19 20 21	 Q. And Dr. Oberlinski is one of FEG's owners; correct? A. That is correct. Q. And he used to work with you at the university; correct? A. This again? Q. He used to work Dr. Oberlinski used to work at the university, didn't he? A. When we started our collaboration, he worked for the institute for textile engineering at the

48 (Pages 186 to 189)

	Page 190		Page 192
1	there are several textile options available to change	1	MR. ANDERSON: Okay. Take a short break.
2	mesh?	2	THE VIDEOGRAPHER: We are off the record.
3	A. Yes.	3	The time is 1:10 p.m.
4	Q. Now, you've been a paid consultant by FEG	4	(A recess was taken from 1:09 p.m. until 1:31 p.m.)
5	since 1998 or 1999. Is that true?	5	THE VIDEOGRAPHER: We are back on the record.
6	A. No. I guess it was later on. It was after	6	The time is 1:31.
7	the contract finished with the with Ethicon.	7	REDIRECT EXAMINATION
8	Q. And to this day you're compensated annually	8	BY MR. ANDERSON:
9	by FEG; correct?	9	Q. Dr. Klinge, do you remember when counsel was
10	A. Correct.	10	asking you some questions about the PVDF mesh and
11	Q. And they pay you about 30,000€ a year?	11	PVDF fibers?
12	A. Yeah.	12	A. There has been several questions, but I
13	Q. They determine how much they'll pay you each	13	remember.
14	year depending on how well the company does that	14	Q. Okay. If we could go to Plaintiff's Exhibit
15	year; correct?	15	697 right here. It's the Otto article. If we could
16	A. Yes.	16	go over a few pages to the mesh.
17	Q. And you've spoken at conferences sponsored	17	MR. ANDERSON: No. Blow up the top part.
18	solely by FEG; correct?	18	Actually, no, no. Next page.
19	A. Yes.	19	MR. KAUFFMANN: Next page?
20	Q. And you do that routinely? You regularly	20	MR. ANDERSON: Okay. Yeah. Blow up the
21	attend conferences around the world on behalf of FEG;	21	whole top part.
22	correct?	22	BY MR. ANDERSON:
23	A. I routinely attend conferences, and I am	23	Q. Doctor, the mesh on the far right side, the
24	invited all over the world. Most of these, far most	24	DynaMesh, is that the mesh that you were talking with
	Page 191		Page 193
_			5
1	of these invitations are not linked to the FEG. So	1	counsel about that's made by FEG?
1 2	of these invitations are not linked to the FEG. So it is an exception if I do it on the on the	1 2	counsel about that's made by FEG? A. Yes. This is a PVDF mesh made by FEG.
		1	
2	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception.	2	A. Yes. This is a PVDF mesh made by FEG.
2	it is an exception if I do it on the on the	2 3	A. Yes. This is a PVDF mesh made by FEG.Q. And does FED FEG make meshes made out of
2 3 4	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't	2 3 4	A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse?
2 3 4 5	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it?	2 3 4 5	A. Yes. This is a PVDF mesh made by FEG.Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse?A. Yes.
2 3 4 5 6	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it? A. Maybe. To be fair, I never have looked to	2 3 4 5 6	 A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse? A. Yes. Q. And just explain quickly for the jury what
2 3 4 5 6 7	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it? A. Maybe. To be fair, I never have looked to this website. I didn't saw any need to do so.	2 3 4 5 6 7	 A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse? A. Yes. Q. And just explain quickly for the jury what PVDF is as a polymer, as a material.
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it? A. Maybe. To be fair, I never have looked to this website. I didn't saw any need to do so. Q. And you're going to teach next week in Baden-Baden at a class sponsored by FEG, aren't you? A. Yeah. Q. The International Masterclass for Laparoscopic Hernia Repair; correct? A. Yes. Q. And that's a seminar sponsored by the FEG? A. Yeah. It was an invitation by Professor Berger, who was the former head of the German Society, and we did it for the fourth time or the fifth time. Q. And the agenda for the hernia session is on	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19	A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse? A. Yes. Q. And just explain quickly for the jury what PVDF is as a polymer, as a material. A. PVDF is a plastic material like as polypropylene is, but it has it consists of two fewer atoms. So it has some other molecules inside, and it has more stability than the polypropylene. Q. How long have you known about PVDF as an alternative polymer to polypropylene for surgical meshes? A. We, actually, started to think about it in 1997. When we finished the Vypro, we knew that it was possible to made a mesh with large pores. But Vypro consists of five filaments, and to reduce further on the risk for bacterial infection, we
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it? A. Maybe. To be fair, I never have looked to this website. I didn't saw any need to do so. Q. And you're going to teach next week in Baden-Baden at a class sponsored by FEG, aren't you? A. Yeah. Q. The International Masterclass for Laparoscopic Hernia Repair; correct? A. Yes. Q. And that's a seminar sponsored by the FEG? A. Yeah. It was an invitation by Professor Berger, who was the former head of the German Society, and we did it for the fourth time or the fifth time. Q. And the agenda for the hernia session is on the FEG website, isn't it?	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20	A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse? A. Yes. Q. And just explain quickly for the jury what PVDF is as a polymer, as a material. A. PVDF is a plastic material like as polypropylene is, but it has it consists of two fewer atoms. So it has some other molecules inside, and it has more stability than the polypropylene. Q. How long have you known about PVDF as an alternative polymer to polypropylene for surgical meshes? A. We, actually, started to think about it in 1997. When we finished the Vypro, we knew that it was possible to made a mesh with large pores. But Vypro consists of five filaments, and to reduce further on the risk for bacterial infection, we wanted to construct it as a monofilament. And,
2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	it is an exception if I do it on the on the invitation of the FEG. This is a rare exception. Q. And your picture is on the FEG website, isn't it? A. Maybe. To be fair, I never have looked to this website. I didn't saw any need to do so. Q. And you're going to teach next week in Baden-Baden at a class sponsored by FEG, aren't you? A. Yeah. Q. The International Masterclass for Laparoscopic Hernia Repair; correct? A. Yes. Q. And that's a seminar sponsored by the FEG? A. Yeah. It was an invitation by Professor Berger, who was the former head of the German Society, and we did it for the fourth time or the fifth time. Q. And the agenda for the hernia session is on the FEG website, isn't it? A. As I told you, I'm not a visitor of this	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21	A. Yes. This is a PVDF mesh made by FEG. Q. And does FED FEG make meshes made out of this PVDF material for pelvic organ prolapse? A. Yes. Q. And just explain quickly for the jury what PVDF is as a polymer, as a material. A. PVDF is a plastic material like as polypropylene is, but it has it consists of two fewer atoms. So it has some other molecules inside, and it has more stability than the polypropylene. Q. How long have you known about PVDF as an alternative polymer to polypropylene for surgical meshes? A. We, actually, started to think about it in 1997. When we finished the Vypro, we knew that it was possible to made a mesh with large pores. But Vypro consists of five filaments, and to reduce further on the risk for bacterial infection, we wanted to construct it as a monofilament. And, therefore, we have been looking for the best material

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	Page 194		Page 196
1	And we approached Ethicon to join this	1	Ethicon?
2	activity further on. We asked for some grants to do	2	A. Yes.
3	this research, and, fortunately, we got the	3	Q. Okay.
4	permission to do this project by our university and	4	MR. ANDERSON: Let's go to Exhibit 3354. Oh,
5	we got some further grants to work on PVDF meshes;	5	it's the wrong one. I need the translation.
6	but, unfortunately, Ethicon denied to develop meshes	6	
7	made of PVDF, though they provided us with one PVDF	7	(Plaintiff's Exhibit No. P3355, English
8	mesh that is made by Ethicon.	8	Translation of Plaintiff's Exhibit 3354, Patent for
9	Q. So did Ethicon have an opportunity to work	9	PVDF mesh, was marked for identification.)
10	with you and FEG to develop PVDF meshes during this	10	
11	time period?	11	BY MR. ANDERSON:
12	A. Obviously they had a mesh, but they didn't	12	Q. I'm showing you what has been marked as
13	want to go into this project to develop PVDF meshes,	13	Plaintiff's Exhibit 3355. What is this, Doctor?
14	but they were asked, but they denied. They didn't	14	A. This is a patent from Ethicon.
15	want to do so.	15	Q. Okay. And what's it a patent for?
16	Q. Have you studied the differences in the	16	A. It's a patent for a PVDF mesh.
17	tissue reaction in patients' tissue of polypropylene	17	Q. Is this something that you've reviewed and
18	versus a PVDF?	18	relied upon in forming some of your opinions here?
19	A. Yeah. We did a several	19	A. Yes.
20	Q. Okay.	20	Q. If you'll turn over to page 12.
21	MR. ANDERSON: Pull up Plaintiff's Exhibit	21	MR. THOMAS: Show my objection to this
22	770, which may help us with this discussion.	22	witness offering any testimony about this
23		23	document. It's well beyond the scope of his
24	(Plaintiff's Exhibit No. PLT0770, Article	24	expertise. The document speaks for itself.
1	entitled "New Polymer for Intra-Abdominal Meshes -	1	There's nothing special he can bring to the
2	PVDF Copolymer", was marked for identification.)	2	issues raised by this patent.
3		3	MR. ANDERSON: Yeah. And I didn't ask him
4	BY MR. ANDERSON:	4	anything about PVDF on direct. You chose to.
5	Q. I'm showing you what's been marked as	5	You opened the door. We're going to drive
6	Plaintiff's Exhibit 0770. Is this some of the	6	through it.
7	research that you were just describing where you were	7	BY MR. ANDERSON:
8	looking at tissue response to PVDF?	8	Q. Okay. So if you will look at page 12 under
9	A. Yes.	9	claims.
10	Q. Okay. Tell the jury what your conclusions	10	A. Yes.
	Q. Okay. Tell the jury what your conclusions were after looking at this PVDF study.	10 11	A. Yes.Q. What does it say with regard to the pore
10	Q. Okay. Tell the jury what your conclusions were after looking at this PVDF study.A. In this study, this study clearly confirms		
10 11	were after looking at this PVDF study.	11	Q. What does it say with regard to the pore
10 11 12	were after looking at this PVDF study. A. In this study, this study clearly confirms	11 12	Q. What does it say with regard to the pore sizes for PVDF mesh?
10 11 12 13	were after looking at this PVDF study. A. In this study, this study clearly confirms that the tissue reaction to the PVDF is better than	11 12 13	Q. What does it say with regard to the pore sizes for PVDF mesh?A. Basic structure should have a pore size with
10 11 12 13 14	were after looking at this PVDF study. A. In this study, this study clearly confirms that the tissue reaction to the PVDF is better than for the polypropylene.	11 12 13 14	Q. What does it say with regard to the pore sizes for PVDF mesh?A. Basic structure should have a pore size with a range of 1.5 to 8.0 millimeter, so to be extremely
10 11 12 13 14 15	were after looking at this PVDF study. A. In this study, this study clearly confirms that the tissue reaction to the PVDF is better than for the polypropylene. Q. Who provided you with the PVDF meshes for	11 12 13 14 15	Q. What does it say with regard to the pore sizes for PVDF mesh?A. Basic structure should have a pore size with a range of 1.5 to 8.0 millimeter, so to be extremely large, covering 90 percent of the total area of the
10 11 12 13 14 15	were after looking at this PVDF study. A. In this study, this study clearly confirms that the tissue reaction to the PVDF is better than for the polypropylene. Q. Who provided you with the PVDF meshes for testing in this study?	11 12 13 14 15 16	Q. What does it say with regard to the pore sizes for PVDF mesh? A. Basic structure should have a pore size with a range of 1.5 to 8.0 millimeter, so to be extremely large, covering 90 percent of the total area of the pores.
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	Page 198		Page 200
1	A. Yes.	1	right there.
2	Q. Okay. From 2008?	2	MR. THOMAS: That's not what it says. I
3	A. From 2008. Ethicon document.	3	object to showing this document to the jury,
4	Q. Okay.	4	admission of this document and any testimony
5	MR. ANDERSON: If you'd go to the slide.	5	about this document. The document speaks by
6	MR. KAUFFMANN: Got it.	6	itself, and this witness is not qualified, with
7	MR. ANDERSON: Yes. Blow up that bottom	7	no foundation to give any comment about the
8	left.	8	document.
9	BY MR. ANDERSON:	9	BY MR. ANDERSON:
10	Q. In this Ethicon presentation, what is this?	10	Q. Dr. Klinge, did you, in fact, have this
11	A. This is a PVDF copolymer mesh.	11	document in your own files when you worked with
12	Q. And do you know and based upon your review	12	Ethicon?
13	of the patent and your review of these documents, did	13	A. Yes.
14	Ethicon have a brand name for this PVDF mesh?	14	Q. And did you produce that to Ethicon when they
15	A. No. I don't think that they marketed it.	15	requested all of your files?
16	O. No. Not marketed it but	16	A. Yes.
17	A. Yeah.	17	Q. So this is a document that you received while
18		18	· · · · · · · · · · · · · · · · · · ·
	Q did they have a brand name for it?A. Brand name was Pronova. Pronova was the name		you were consulting with them? A. Yes.
19		19	
20	of this.	20	Q. Great. And underneath there it says
21	Q. Do you have any information as to whether or	21	Christoph Walther. Is that one of the Ethicon
22	not Ethicon ever chose to sell their Pronova mesh	22	employees that you would have worked with?
23	made out of PVDF?	23	A. Yes.
24	A. So far I know, they never brought it to the	24	Q. And in the middle there where it says,
	Page 199		Page 201
1	market.	1	"Pronova monofilaments are an extremely good
2	Q. And from your reading of the PowerPoint, what	2	candidate as implant material, very high flexibility
3	was the discussion and the reason for this PowerPoint	3	and low bending stiffness"
4	being given at Ethicon?	4	A. Yes.
5	MR. THOMAS: Objection; state of mind,	5	Q "and without loss of tensile strength in
6	knowledge of Ethicon.	6	contrast to polypropylene and long-term stability
7	BY MR. ANDERSON:	7	long-term stability in human body."
8	Q. What was discussed in this Thunder PowerPoint	8	Do you agree with those statements by
9	by Ethicon?	9	Ethicon?
10	MR. THOMAS: Same objection.	10	A. Yes.
	THE WITNESS: The entire project was to	11	Q. Do you have an opinion as to whether or not
11		1	2. Do you have an opinion as to whether of hot
11 12	1 0	12	nolynronylene mesh is creates greater inflammatory
12	evaluate whether the use of PVDF would make a	12	polypropylene mesh is creates greater inflammatory
12 13	evaluate whether the use of PVDF would make a safer approach would make a safer device for	13	reaction in tissues than PVDF mesh?
12 13 14	evaluate whether the use of PVDF would make a	13 14	reaction in tissues than PVDF mesh? A. Polypropylene in general produces more
12 13 14 15	evaluate whether the use of PVDF would make a safer approach would make a safer device for the use in the pelvic floor.	13 14 15	reaction in tissues than PVDF mesh? A. Polypropylene in general produces more inflammation, more scarring than PVDF.
12 13 14 15 16	evaluate whether the use of PVDF would make a safer approach would make a safer device for the use in the pelvic floor. (Plaintiff's Exhibit No. P3184, Letter to	13 14 15 16	reaction in tissues than PVDF mesh? A. Polypropylene in general produces more inflammation, more scarring than PVDF. Q. You were asked by Mr. Thomas on
12 13 14 15 16 17	evaluate whether the use of PVDF would make a safer approach would make a safer device for the use in the pelvic floor. (Plaintiff's Exhibit No. P3184, Letter to Quentin from Christoph Walther, Bates stamped	13 14 15 16 17	reaction in tissues than PVDF mesh? A. Polypropylene in general produces more inflammation, more scarring than PVDF. Q. You were asked by Mr. Thomas on cross-examination whether polypropylene has been used
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12 13 14 15 16 17 18 19 20 21	evaluate whether the use of PVDF would make a safer approach would make a safer device for the use in the pelvic floor. (Plaintiff's Exhibit No. P3184, Letter to Quentin from Christoph Walther, Bates stamped HMESH_ETH_00379723, was marked for identification.) BY MR. ANDERSON: Q. Let's look at Plaintiff's Exhibit 3184. This	13 14 15 16 17 18 19 20 21	reaction in tissues than PVDF mesh? A. Polypropylene in general produces more inflammation, more scarring than PVDF. Q. You were asked by Mr. Thomas on cross-examination whether polypropylene has been used in the human body for hernia mesh since 1962. Do you remember that question? A. Yes. Q. And has polypropylene been used in the human

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	Page 202		Page 204
1	suture material and asked you whether or not that	1	Q. Go right ahead, Doctor.
2	much material goes into some of the meshes in the	2	A. When using when I would use a new device,
3	hernia for hernia repair. Do you remember that	3	I'm dependent on the information that is provided by
4	part of your questioning?	4	the manufacturer for the long-term risks or for the
5	A. Yes.	5	risks that are connected to this device. There is no
6	Q. Is there a difference between that amount of	6	other way to get this information.
7	material in the abdominal wall than that amount of	7	Q. If you're a surgeon that's putting in what
8	material in a woman's vaginal space?	8	you characterize as a relatively new device, if the
9	A. Definitely. The use of a mesh in the	9	manufacturer knew that there was a serious long-term
10	abdominal wall, we don't have to consider some	10	risk of chronic debilitating pain, would you expect
11	forces. It's laying there flat, usually beneath the	11	them to pass that information along to you?
12	muscles. You don't have any tension to any arms or	12	A. Yes, I would.
13	something like this. There are less nerves. There	13	MR. THOMAS: Objection to foundation.
14	are no organs with direct contact to the mesh that	14	THE WITNESS: And in parallel, he has to stop
15	can be damaged by this. So it is more easy if you	15	selling it.
16	have some complications, some infection, it is	16	BY MR. ANDERSON:
17	quite much more easy to remove it and to repair	17	O. And if a manufacturer was aware of serious
18	the damage after a mesh complication.	18	adverse events of life-altering untreatable erosions,
19	Q. Easier to remove the hernia than the pelvic	19	would you expect them to pass that along to you as a
20	organ prolapse, is that what you're saying?	20	surgeon?
21	A. It is easier to remove the mesh.	21	MR. THOMAS: Objection.
22	MR. THOMAS: Let me move to strike his	22	A. Yes.
23	testimony about mesh in the pelvic floor as being	23	MR. THOMAS: Argumentative.
24	beyond the area of his expertise.	24	BY MR. ANDERSON:
21	beyond the area of his expertise.		BT WICH BELOOK
		T .	
	Page 203		Page 205
1	Page 203 MR. ANDERSON: You sure asked him a lot of	1	Page 205 Q. Okay. Wait until he does his objection
1 2	_	1 2	
	MR. ANDERSON: You sure asked him a lot of		Q. Okay. Wait until he does his objection
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2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	MR. ANDERSON: You sure asked him a lot of questions about it, but okay. Let's move on. BY MR. ANDERSON: Q. You were asked some questions about consenting your patients when you were a hernia surgeon. Do you remember that? A. Yes. Q. And you were asked questions about what risks you would pass along to your patients; correct? A. Yes. Q. Can you pass along a risk if you're not told about it by the manufacturer? A. No. Q. If you were a surgeon who's implanting a new surgical device, do you expect the manufacturer to pass along information they have about serious adverse events that could affect that risk-benefit discussion with your patients? A. Definitely. MR. THOMAS: Objection; foundation, beyond the scope. MR. ANDERSON: It's direct response to the	2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22	 Q. Okay. Wait until he does his objection A. Sorry. Q and then you can answer because it's messing up the record, and it's harder for her to type. A. Sorry. MR. THOMAS: Do you want to ask the question again? MR. ANDERSON: I think I liked it. THE COURT REPORTER: You might need to MR. ANDERSON: Because he interrupted me? MR. THOMAS: I didn't want mean to. MR. ANDERSON: Well, you already did. MR. THOMAS: I'm sorry. Doing the best I can, man. BY MR. ANDERSON: Q. If a manufacturer is aware of serious lifelong risk of recurrent erosions that can't be treated, would you, as a surgeon, want to know that? A. Yes. Q. If a manufacturer is aware that their product

	Page 206		Page 208
1	A. Yes.	1	THE WITNESS: There is no way to place it
2	Q. If a manufacturer was aware that in certain	2	completely tension-free, and I believe there is
3	patients, like young patients or sexually active	3	no one who will really think of it as an option.
4	patients, that in those patients they shouldn't have	4	BY MR. ANDERSON:
5	that device implanted, would you expect them to pass	5	Q. When you saw those arms being pulled through
6	that along to you?	6	the woman's groin from her vaginal incision, was
7	A. Yes.	7	there tension being placed on those arms?
8	MR. THOMAS: Just show my objection to the	8	A. Definitely. Uniaxial tension, as it was done
9	whole line as being beyond his whole line of	9	in our measurements and it was done as it was done
10	expertise as a hernia surgeon.	10	in the drawings from Ethicon and in the study done by
11	MR. ANDERSON: And that's fine because, just	11	Ethicon.
12	for the judge's purposes when we go to argue	12	Q. And Mr. Thomas mentioned that when you did
13	this, Mr. Thomas asked numerous questions about	13	your uniaxial testing with Professor Mühl that you
14	passing on the risk-benefit information and that	14	held one end and you pulled on the other end;
15	the manufacturer didn't need to tell him these	15	correct?
16	things because he already knew it; and so let's	16	A. Yes.
17	go through some of the things on redirect of what	17	Q. Is that exactly what the surgeon was doing in
18	he would like to know from the manufacturer, and	18	that DVD video with the arms?
19	so that's what I'm attempting to do now. So	19	A. Yes.
20	we'll note your objection and my response.	20	Q. You were asked some questions about your
21	BY MR. ANDERSON:	21	testing with Professor Mühl by Mr. Thomas about
22	Q. If the manufacturer is aware that their	22	whether or not this the porosity setup and
23	device should not be used with certain patients,	23	investigation you had done accounted for pelvic floor
24	certain indications, would you expect them to pass	24	forces. Do you remember that?
	Page 207		Page 209
1	that information along to you?	1	A. Yes.
2	A. Yes.	2	Q. As you looked at the pores in the DVD and the
3	MR. THOMAS: Objection; vague.	3	tension placed on the mesh arms by the surgeon, are
4	THE WITNESS: Yes, of course.	1 1	
		4	those pores deformed before any forces from the
5	BY MR. ANDERSON:	5	pelvis are being placed on the mesh?
6	BY MR. ANDERSON: Q. For instance, if a manufacturer knew that a	5 6	pelvis are being placed on the mesh? MR. THOMAS: Objection. Again, not familiar
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Page 212 Page 210 1 He also -- Mr. -- the counsel also pointed 1 experimental results. And if you have another 2 out from these articles -- he pointed out to two 2 polymer, yeah, you have to adopt it to this polymer 3 sections on the 2007 article and the 2013 article, 3 after having the -- making this investigation. 4 these sections that says clinical studies have to 4 Q. Thank you. Let me go to another question 5 prove whether or not effective porosity and meshes 5 he -- series of questions you were asked. 6 with high effective porosity will actually result in 6 He put two articles in front of you by Jan 7 improved patient complications. Do you remember 7 Deprest, and counsel said, "Are you aware of other that? 8 8 scientists out there who may disagree with your 1 9 A. Yes. 9 millimeter?" Do you remember that part of the 10 Q. And he asked you, "You haven't done any 10 questioning? clinical studies to look at this, have you?" Do you 11 11 A. Yes. 12 recall that question? 12 Q. Those two articles by Jan Deprest, is Jan 13 A. Yes. 13 Deprest an Ethicon consultant? 14 Q. Are you a mesh manufacturer, Doctor? 14 A. So far I know, yes. 15 A. No. 15 Q. And if Jan Deprest said that 75 microns is 16 16 Q. After Ethicon circulated these two e-mails in efficient for good, healthy tissue ingrowth and it 17 2008 and again in 2010, circulating your and Mühl's 17 will resist scar plates, is that consistent or 18 testing, did you see anywhere in the Ethicon 18 inconsistent with Ethicon's own documents? 19 documents where they did any clinical studies to look 19 MR. THOMAS: Object to the form of the 20 at pore deformation? 20 question. Object to foundation. 21 A. No, I didn't find any hint for this. 21 THE WITNESS: It will be inconsistent. If 22 Q. Do you see anywhere in the documents, all the 22 you really believe that it is possible to -- or 23 thousands of documents you reviewed, all the 23 the ingrowths of healthy tissue is possible for 24 depositions of all the Ethicon witnesses you 24 these low pore size, then it would be Page 213 Page 211 1 reviewed, or any scientific literature where Ethicon 1 inconsistent. The Ethicon people clearly stated 2 ever looked at what the impact on patients would be 2 it on several pages in several documents that we 3 3 after forces were placed on the arms? Do you see have to consider a pore size of 3 millimeters or 4 4 at least 1 millimeter and far beyond. that anywhere? 5 5 A. No. BY MR. ANDERSON: 6 Q. You were asked why your machine was set for 6 Q. And was the product that was developed by you 7 1,000 microns for polypropylene in terms of a 7 and Ethicon, the Vypro mesh, did it have pore sizes 8 critical limit of the distance between the fibers, 8 less than 75 microns? and you were asked why PVDF was set at 600 microns. 9 9 A. No. 10 10 Do you remember that? Q. Did it have pore sizes larger than 1,000 A. Yes. 11 11 microns? 12 12 Q. Why? A. So the pores -- the area of the large pores 13 A. The basis for these two figures, 600 and 13 is considerably higher, and the diameter of these 14 1,000 microns, have been our investigations of the 14 pores is between 3 and 5 millimeter. 15 15 tissues, because we have seen that around the fiber Q. Have you seen anywhere in the Ethicon 16 made of PVDF, the inflammatory reaction is -- is 16 documents out of all of the ones you've reviewed or 17 attenuated and there is less scar and that the pores 17 out of the ten years of consulting with them or all 18 18 are filled with fat even when the size of the hole of of the depositions that you saw anywhere where 19 the pore is only 600 microns. And, therefore, 19 Ethicon said, "At 75 microns we can prevent fibrotic 20 because this -- this measurement by Professor Mühl 20 bridging"? 21 21 was intended to predict the risk for these scar A. Nowhere. 22 contraction and scar integration in the pores; 22 Q. You were asked another series of questions 23 therefore, we adopted this to 600 microns for PVDF 23 about whether there were any RCTs that you could 24 and 1 millimeter for polypropylene. It fits to our 24 point to randomized controlled trials of Prolift in

	Page 214		Page 216
1	order to prove the safety of its device. Do you	1	A. It's healthy tissue in healthy rats.
2	remember that?	2	Q. Is it being used with trocars and cannulas to
3	A. Yes.	3	pull it in there?
4	Q. You were asked whether you had conducted any	4	A. No trocars.
5	studies or knew of any studies, randomized controlled	5	Q. Is it going in through a transvaginal
6	trials, to prove the safety of Prolift. Do you	6	incision of the rat?
7	remember that?	7	A. No, nothing like this.
8	A. Yes.	8	Q. Is it being permanently implanted in the
9	Q. Do you see anywhere where Ethicon conducted	9	rat's tissue?
10	their own safety studies in order to look as to	10	A. It's only implanted for 90 days.
11	whether or not this amount of material was actually	11	Q. Were any forces placed on the mesh during the
12	necessary to support a woman's pelvic organs?	12	implanting or being forced any forces on the mesh
13	A. No.	13	after implantation?
14	Q. Did you see anywhere where Ethicon did any	14	A. No. When placing in the subcutaneous area,
15	clinical trials to determine whether or not the pore	15	you don't have any forces.
16	sizes of Gynemesh PS were necessary to be that size	16	Q. Is the subcutaneous skin in the back of a rat
17	in order to support pelvic organ prolapse?	17	the same as the delicate pelvic tissues of a woman?
18	A. No.	18	A. No. It is the tissue reaction of pure fat
19	Q. Did you see anywhere where Ethicon justified	19	is attenuated.
20	or clinically studied that it was necessary for them	20	Q. When Prolift or any other pelvic organ
21	to have pores that would collapse and look like the	21	prolapse mesh is put into a woman's tissue, is that
22	deformed pores on the DVD in order to be safely	22	because it's healthy or unhealthy?
23	implanted in a woman?	23	MR. THOMAS: Objection.
24	MR. THOMAS: Objection; argumentative.	24	THE WITNESS: Unhealthy.
	Page 215		Page 217
1	BY MR. ANDERSON:	1	BY MR. ANDERSON:
2	Q. Did you see that?	2	Q. And is it being permanently implanted or
3	A. No.	3	implanted for 91 days?
4	Q. You were asked a whole lot of questions about	4	A. It's permanently for years hopefully.
5	this 91-day rat study, so let's talk about a rat	5	Q. And are these rats having sexual relations
6	study if we could. That was an internal Ethicon	6	while they have the mesh in their back?
7	study; correct?	7	MR. ANDERSON: I would like to withdraw that
8	A. Yes.	8	question.
9	Q. Done by Ethicon scientists?	9	THE WITNESS: I think so.
10			DVAID ANDEDGOV
	A. Yes.	10	BY MR. ANDERSON:
11	Q. Was it peer-reviewed in the peer-reviewed	11	Q. Let me ask you this, Doctor.
11 12	Q. Was it peer-reviewed in the peer-reviewed publications?	11 12	Q. Let me ask you this, Doctor.Would it be safe to take a three-month study
11 12 13	Q. Was it peer-reviewed in the peer-reviewed publications?A. No.	11 12 13	Q. Let me ask you this, Doctor. Would it be safe to take a three-month study of a piece of mesh that's the size of your fingernail
11 12 13 14	Q. Was it peer-reviewed in the peer-reviewed publications?A. No.Q. The size of the piece of mesh, can you just	11 12 13 14	Q. Let me ask you this, Doctor. Would it be safe to take a three-month study of a piece of mesh that's the size of your fingernail that was in the back of a rat where no trocars were
11 12 13 14 15	Q. Was it peer-reviewed in the peer-reviewed publications?A. No.Q. The size of the piece of mesh, can you just show the jury what the size of the piece of mesh	11 12 13 14 15	Q. Let me ask you this, Doctor. Would it be safe to take a three-month study of a piece of mesh that's the size of your fingernail that was in the back of a rat where no trocars were used in healthy tissue, not going through a
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	Dama 210		Page 220
	Page 218		Page 220
1	showing that the material has an impact on the tissue	1	CERTIFICATE
2	ingrowth. So if you make your own study and seeing	2	
3	no difference in these small group of animals, then	3	I, Tami Cline, Registered Merit Reporter,
4	you should think of exchanging the people who are	4	Certified Realtime Reporter, and Florida Professional
5	responsible for this study. It is yeah.	5	Reporter, do hereby certify that, pursuant to notice,
6	Q. So counsel asked you on cross-examination	6	the deposition of PROF. DR. MED. UWE KLINGE was duly
7	he said, "You have not designed a device that was	7	taken on November 10, 2014, at 9:04 a.m. before me.
8	designed for the for pelvic organ prolapse." Do	8	The said PROF. DR. MED. UWE KLINGE was duly
9	you remember that question?	9	sworn by me according to law to tell the truth, the
10	A. I remember it.	10	whole truth and nothing but the truth and thereupon
11	Q. Has Ethicon ever designed a mesh that was	11	did testify as set forth in the above transcript of
12	specifically designed for the pelvic floor?	12	testimony. The testimony was taken down
13	A. No.	13	stenographically by me. I do further certify that
14	Q. You were asked three different questions that	14	the above deposition is full, complete, and a true
15	I want to go to, Doctor. You were asked at the	15	record of all the testimony given by the said
16	beginning of your cross-exam, "91 percent of all	16	witness.
17	surgical meshes on the market today are made of	17	
18	polypropylene." Do you remember that question?	18	
19	A. Yes.	19	Tami Cline, RMR, CRR, FPR
20	Q. And do you remember the question of, "Can you	20	
21	think of any product on the market today that is	21	(The foregoing certification of this
22	safer than Prolift for pelvic organ prolapse?" Do	22	transcript does not apply to any reproduction of the
23	you remember those questions?	23	same by any means, unless under the direct control
24	A. Yes.	24	and/or supervision of the certifying reporter.)
	Page 219		Page 221
1	Page 219 Q. Is Prolift or Prolift+M still on the market	1	Page 221 INSTRUCTIONS TO WITNESS
1 2	Q. Is Prolift or Prolift+M still on the market	1 2	
2	Q. Is Prolift or Prolift+M still on the market today? MR. THOMAS: Objection.	2	INSTRUCTIONS TO WITNESS
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	Page 22
	ERRATA
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	REASON:
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	Page 22
	ACKNOWLEDGMENT OF DEPONENT
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	I,, do hereby
ŀ	acknowledge that I have read the foregoing pages, 1
,	to 224, and that the same is a correct transcription
	of the answers given by me to the questions therein
	propounded, except for the corrections or changes in
3	form or substance, if any, noted in the attached
	Errata Sheet.
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2	PROFE DRIVER AWARD AND A TELE
3	PROF. DR. MED. UWE KLINGE DATE
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. 7	Subscribed and sworn to before me this
9	day of, 20
0	My Commission expires:
21	, commonton expires.
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	Notary Public
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